EXHIBIT A
(Filed Under Seal)

EXHIBIT B

MARCH 15, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In re: Bard IVC Filters, Products Liability Litigation	
	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v.	Phoenix, Arizona March 15, 2018
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	CV-16-00474-PHX-DGC 12:59 p.m.

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 2 P.M.

(Pages 337 through 444)

Official Court Reporter:
Elaine Cropper, RDR, CRR, CCP
Sandra Day O'Connor U.S. Courthouse
401 West Washington Street
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director from Bard. He was there from 2004 through 2008 or '9 02:19:14
but he was there during the period.

MR. NORTH: My only correction is he's still employed there today.

MR. LOPEZ: Oh. Okay. 02:19:28

THE COURT: You can begin playing the deposition.

This should be on your screen, ladies and gentlemen and you should be able to hear it.

(Whereupon, videotaped deposition of Dr. David Ciavarella was played for the jury.) 02:20:52

THE COURT: All right. Let's stop the deposition at this point.

Latches, we'll take the afternoon break. We will plan to resume at a quarter to three. We'll excuse you at this time. 02:29:46

(Jury departs at 2:29.)

THE COURT: Counsel, let me remind you of what I said in an order that came out last week. We're not having the court reporters transcribe what is being played on the deposition. So you should be sure to put in the record an 02:30:22
agreed-upon statement of what portions of the depositions were read so that it's clear on appeal.

This portion we just watched showed a document which the jury has seen and it was asked about. There's been no discussion that I know of moving that into evidence. If so, 02:30:40

Designation Run Report

Civarella 11-12-13 Booker Depo Designations Final2

Ciavarella, David 11-12-2013

Plaintiffs Designations 00:20:49

Defense Designations 00:08:35

P & D Affimatives 00:09:54

Total Time 00:39:18

Page/Line	Source	ID
	106:9 Q. I'm just trying to find out 106:10 from you what your position and Bard's position 106:11 is about the significance of what is being 106:12 reported and trended via the MAUDE database. 106:13 A. Well -- 106:14 Q. Can you tell me what that is? 106:15 A. -- with respect to our own reports 106:16 that we provide to the MAUDE database, we 106:17 already know that information. So whether that 106:18 information goes to the MAUDE database or not, 106:19 Bard has access to that information and can use 106:20 it to assure the quality of its product. 106:21 With respect to our competitors' 106:22 information, it's a very imperfect and, 106:23 therefore, unreliable database.	
110:21 - 111:3	**Ciavarella, David 11-12-2013 (00:00:23)** 110:21 Q. Again, looking at Exhibit 110:22 21, this is the -- at least the internal 110:23 document that should have guided Bard in its 110:24 assessment and evaluation and determination as 110:25 to whether or not the Recovery or any version of 111:1 the G2 should have been recalled from the 111:2 market; is that right? 111:3 A. Yes.	03_12_18 Combo final2.22
131:6 - 131:12	**Ciavarella, David 11-12-2013 (00:00:15)** 131:6 Q. But there's a general consensus 131:7 that that might be, in fact, the case, you're 131:8 only getting 1 to 5 percent of what's actually 131:9 happening, actually reported to the company or 131:10 FDA? 131:11 A. I mean, maybe yes, maybe no. That's 131:12 the problem with it is you don't know.	03_12_18 Combo final2.23
131:16 - 131:23	**Ciavarella, David 11-12-2013 (00:00:19)** 131:16 Q. But there was at one point in 131:17 time -- I can show you the document later -- 131:18 where you, Dr. Ciavarella, said one of the 131:19 problems with reporting of events, voluntary 131:20 reporting, is there's a consensus that you might 131:21 be only getting 1 to 5 percent of the actual 131:22 events; right?	03_12_18 Combo final2.24

Page/Line	Source	ID
	131:23 A. Could be. Yeah, there's a consensus.	
174:22 - 175:9	**Civarella, David 11-12-2013 (00:00:50)** 174:22 Q. let's look at the caval 174:23 perforation issue that we talked about earlier 174:24 as it relates to the G2. If you look at the 174:25 rates -- by the way, that does say "Rates," 175:1 doesn't it, in the column? They use the word 175:2 "Rates"? 175:3 A. Down at the bottom they do, yeah. 175:4 Q. Okay. And according to this data, the 175:5 rates of caval perforations compared to the SNF 175:6 and the G2, is the G2 is still, at least 175:7 according to this data, about -- what's that, 175:8 about 800 percent greater? 175:9 A. No.	03_12_18 Combo final2.25
175:10 - 175:12	**Civarella, David 11-12-2013 (00:00:02)** 175:10 Q. I'm just asking you to do some math 175:11 with me. 175:12 A. You're misinterpreting the data.	03_12_18 Combo final2.26
176:2 - 176:8	**Civarella, David 11-12-2013 (00:00:14)** 176:2 Q. If you 176:3 look at the difference between the rates that 176:4 are reported on this document, the rates of 176:5 caval perforations are greater for the G2 when 176:6 compared to both the Recovery and the Simon 176:7 Nitinol filter? 176:8 A. Yes.	03_12_18 Combo final2.27
179:16 - 179:25	**Civarella, David 11-12-2013 (00:00:32)** 179:16 Q. Well, eventually didn't Dr. Lehmann 179:17 take some of this data -- I don't know what time 179:18 period it was -- the MAUDE data, and determine 179:19 that there was a statistically significant 179:20 increased risk of migration, perforation, 179:21 fractures, and other complications involved with 179:22 the Recovery filter when compared to all other 179:23 filters on the market by a factor of somewhere 179:24 between the low 4s and the mid 5s? 179:25 A. Yeah.	03_12_18 Combo final2.28
180:2 - 180:9	**Civarella, David 11-12-2013 (00:00:28)** 180:2 A. He did an analysis based on reported	03_12_18 Combo final2.29

EXHIBIT C

March 20, 2018 - P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 20, 2018 12:59 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 4 P.M.

(Pages 780 through 899)

Official Court Reporter:
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exhibits that will be appearing in the video that I would like to read off and move into evidence. 04:07:17

Trial Exhibit 2244, which is D'Ayala Exhibit Number 2 at his deposition; Trial Exhibit 2057 is Exhibit 3 to his deposition; trial Exhibit 994, which is Exhibit Number 4 to his deposition; Trial Exhibit 2321, which is Exhibit Number 8 to his deposition; and Trial Exhibit 1001 which is Exhibit 13 to his deposition. 04:07:36

THE COURT: And are you moving those into evidence?

MS. REED ZAID: Yes, sir. 04:07:58

THE COURT: Any objection?

MS. HELM: No, Your Honor.

THE COURT: All right. Those exhibits will admitted. And you may play the deposition.

(Exhibit Numbers 2244, 2057, 994, 2321, 1001 were admitted into evidence.) 04:08:04

MS. REED ZAID: Thank you.

(Whereupon the deposition of Dr. D'Ayala was played.)

THE COURT: All right. Counsel. Let's stop the video there. 04:19:47

All right. We are at 4:20, ladies and gentlemen. We will plan to begin tomorrow morning at nine and we will excuse the jury at this time.

(Jury departs at 4:20.)

THE COURT: Please be seated. 04:20:22

Designation Run Report

D'Ayala 03-21-17 Booker Depo Designation Final3.1

D, ayala 03-21-2017

Plaintiffs Designations 00:23:55

Defense Designations 00:16:37

Plaintiffs and defense Designations 00:00:50

Total Time 00:41:22

Page/Line	Source	ID
	21:11 there's potential for a serious injury or death, 21:12 correct? 21:13 A. Yes.	
21:21 - 22:5	**D, ayala 03-21-2017 (00:00:27)** 21:21 Q. Let me ask you about the 21:22 frequency of risk, and that is, the risk of serious 21:23 injury or death. 21:24 Is it important to you, as a treating 21:25 doctor that implants devices in a patient, what the 22:1 frequency of that risk is, whether it's one in a 22:2 million or one in ten? Is that an important -- is 22:3 that important information for you in determining 22:4 the risk versus benefit analysis? 22:5 A. Yes.	03_20_18 combo final3_1.6
23:2 - 23:5	**D, ayala 03-21-2017 (00:00:10)** 23:2 Is it important to you, as a 23:3 clinician that implants medical devices, to know the 23:4 frequency of which a device fails? 23:5 A. Yes.	03_20_18 combo final3_1.7
23:15 - 23:24	**D, ayala 03-21-2017 (00:00:30)** 23:15 Q. What about the risk of 23:16 serious injury, that is, the severity of the injury? 23:17 Is that also important for you to know, when doing a 23:18 risk/benefit analysis, whether you use a product or 23:19 not? 23:20 A. Yes. 23:21 Q. And those two individual points of 23:22 analysis, that is, frequency and severity of adverse 23:23 events, both of those are used in your prescribing 23:24 decisions?	03_20_18 combo final3_1.8
24:1 - 24:5	**D, ayala 03-21-2017 (00:00:13)** 24:1 THE WITNESS: Yes. 24:2 BY MR. MATTHEWS: 24:3 Q. Doctor, you only saw Ms. Booker in 24:4 June of 2007; is that correct? 24:5 A. Yes.	03_20_18 combo final3_1.9
26:7 - 27:12	**D, ayala 03-21-2017 (00:01:50)** 26:7 Q. So oftentimes, you'll treat a patient 26:8 and implant a filter, as an example, or a stent, and 26:9 that may be the only time that you see that patient?	03_20_18 combo final3_1.10

Page/Line	Source	ID
	30:6 Sinai Hospital in '97, '98.	
31:13 - 31:16	**D, ayala 03-21-2017 (00:00:07)**	03_20_18 combo final3_1.13
	31:13 Q. You said you moved away from the Bard	
	31:14 filter because of problems associated with it,	
	31:15 correct?	
	31:16 A. Yes.	
31:19 - 32:1	**D, ayala 03-21-2017 (00:00:22)**	03_20_18 combo final3_1.14
	31:19 Q. What were the problems associated	
	31:20 with the Bard that -- the reason that you moved away	
	31:21 from it?	
	31:22 A. There is a database known as the	
	31:23 MAUDE database and it was becoming clear that there	
	31:24 were numerous reports in the literature of filter	
	31:25 fragmentation and filter migration with these	
	32:1 filters.	
32:8 - 32:12	**D, ayala 03-21-2017 (00:00:10)**	03_20_18 combo final3_1.15
	32:8 Q. Were you called upon by a sales rep	
	32:9 or somebody that's known as a detailer from Bard	
	32:10 that came to your hospital to talk to you --	
	32:11 A. Yes.	
	32:12 Q. -- about their filters?	
32:19 - 32:20	**D, ayala 03-21-2017 (00:00:01)**	03_20_18 combo final3_1.16
	32:19 Do you recall a sales rep by the name	
	32:20 of Ferrara?	
32:23 - 32:25	**D, ayala 03-21-2017 (00:00:07)**	03_20_18 combo final3_1.17
	32:23 A. I do.	
	32:24 Q. Was he in your offices from time to	
	32:25 time to talk about the Recovery and the G2?	
33:3 - 33:3	**D, ayala 03-21-2017 (00:00:00)**	03_20_18 combo final3_1.18
	33:3 A. Yes.	
33:7 - 33:13	**D, ayala 03-21-2017 (00:00:18)**	03_20_18 combo final3_1.19
	33:7 Q. Were you ever told by Mr. -- is it	
	33:8 Ferrara?	
	33:9 A. Uh-huh.	
	33:10 Q. -- Mr. Ferrara that Bard had a crisis	
	33:11 management plan, as early as 2004, to deal with the	
	33:12 high rates of AEs, that being, adverse events,	
	33:13 perforation, fracture and migration?	
33:15 - 33:20	**D, ayala 03-21-2017 (00:00:18)**	03_20_18 combo final3_1.20
	33:15 THE WITNESS: No.	

Page/Line	Source	ID
	33:16 BY MR. MATTHEWS: 33:17 Q. Were you ever told that Bard 33:18 conducted an investigation in 2004 into the high 33:19 number or large number of adverse events of the 33:20 Recovery done by an independent investigator?	
33:22 - 34:3	**D, ayala 03-21-2017 (00:00:12)** 33:22 THE WITNESS: No. 33:23 BY MR. MATTHEWS: 33:24 Q. Were you ever sent a letter by the 33:25 company that talked to you or -- I'm sorry, that 34:1 informed you about the results of this 34:2 investigation, this independent investigation by 34:3 Bard?	03_20_18 combo final3_1.21
34:5 - 34:10	**D, ayala 03-21-2017 (00:00:13)** 34:5 THE WITNESS: No. 34:6 BY MR. MATTHEWS: 34:7 Q. Were you ever told, either by letter 34:8 or by Mr. Ferrara, that there was a 530 percent 34:9 higher fracture rate than other filters on the 34:10 market with the Bard Recovery?	03_20_18 combo final3_1.22
34:12 - 34:17	**D, ayala 03-21-2017 (00:00:12)** 34:12 THE WITNESS: No. 34:13 BY MR. MATTHEWS: 34:14 Q. Were you ever told that there was a 34:15 1,200 percent higher risk of death from the Recovery 34:16 fracture and embolization to the heart than other 34:17 filters on the market?	03_20_18 combo final3_1.23
34:19 - 35:2	**D, ayala 03-21-2017 (00:00:20)** 34:19 THE WITNESS: No. 34:20 BY MR. MATTHEWS: 34:21 Q. In 2004 and 2005, clearly two years 34:22 prior to implanting Ms. Booker with the G2, would 34:23 that have been important information for you to 34:24 know? Assuming that that was information that was 34:25 known to Bard, is that something that you would want 35:1 to have known? 35:2 A. Yes.	03_20_18 combo final3_1.24
37:22 - 37:24	**D, ayala 03-21-2017 (00:00:08)** 37:22 Q. Let me show you what's been marked as 37:23 Exhibit-3, which is the Recovery filter migration,	03_20_18 combo final3_1.25 DAYALA 3.1.2 DAYALA 3.1.1

Page/Line	Source	ID
	44:22 and addressed.	
	44:23 BY MR. MATTHEWS:	
	44:24 Q. At a bare minimum, the MAUDE database	
	44:25 would be a signal, a red flag --	
45:2 - 45:6	**D, ayala 03-21-2017 (00:00:08)**	03_20_18 combo final3_1.33
	45:2 BY MR. MATTHEWS:	
	45:3 Q. -- a red flag that should cause and	
	45:4 promote more research into whether a product is safe	
	45:5 and effective?	
	45:6 A. Agree.	
47:2 - 47:7	**D, ayala 03-21-2017 (00:00:16)**	03_20_18 combo final3_1.34
	47:2 Q. But let me ask you, then, this	
	47:3 question, just so we're clear.	
	47:4 Do you rely, in part, on IFUs, that	
	47:5 is, instructions for use, with the products you	
	47:6 implant in patients?	
	47:7 A. Yes.	
47:13 - 47:15	**D, ayala 03-21-2017 (00:00:09)**	03_20_18 combo final3_1.35
	47:13 MR. MATTHEWS: All right. I would	DAYALA 4.1.3
	47:14 like to mark as Exhibit-4 an IFU from the G2 filter	
	47:15 system that, on the last page, is dated 10/06.	
48:11 - 49:8	**D, ayala 03-21-2017 (00:00:53)**	03_20_18 combo final3_1.36
	48:11 Q. Doctor, I'd like to -- I don't mean	clear
	48:12 to interrupt you, but I would like to ask a couple	
	48:13 of specific questions about this.	
	48:14 A. Please do.	
	48:15 Q. On the second -- on the right-hand	DAYALA 4.1
	48:16 column, under 7, there is a -- under E, warning, G2	
	48:17 Filter implantation, it says, Filter fracture is a	DAYALA 4.1.1
	48:18 known complication of vena cava filters.	
	48:19 Do you see that?	
	48:20 A. I do.	
	48:21 Q. It says, There have been -- There	
	48:22 have been reports of embolization of vena cava	
	48:23 filter fragments resulting in retrieval of the	
	48:24 fragment using endovascular and/or surgical	
	48:25 techniques. Most cases of filter fracture, however,	
	49:1 have been reported without any adverse clinical	
	49:2 sequelae.	
	49:3 I'd like to ask you about the first	DAYALA 4.1.2

Page/Line	Source	ID
	61:21 had a fivefold increased risk for fracture compared 61:22 to other filters. 61:23 BY MR. MATTHEWS: 61:24 Q. In 2007 would you have implanted that 61:25 filter?	
62:5 - 62:24	**D, ayala 03-21-2017 (00:01:08)** 62:5 THE WITNESS: The PREPIC 1 trial is a 62:6 great study, and it's a very interesting study. But 62:7 there are problems in this study, as there are 62:8 problems with every study. And the fundamental 62:9 problem that you have with this trial is that it 62:10 randomized patients who were candidates for caval 62:11 interruption or not; in other words, all patients 62:12 were treated with blood thinners. It doesn't really 62:13 address the question of what to do with those 62:14 patients that cannot be treated with blood thinners. 62:15 And from my review of the chart on 62:16 Ms. Booker, it was clear that she could not be 62:17 treated with blood thinners. The reason for that 62:18 was she had bleeding complications. She was, if I 62:19 recall, anemic, and she was to undergo subsequent 62:20 surgical interventions. 62:21 So her anticoagulation had to be 62:22 held, hence, PREPIC doesn't really apply to a 62:23 patient like Ms. Booker. It applies to a different 62:24 set of patients.	03_20_18 combo final3_1.50
62:25 - 63:20	**D, ayala 03-21-2017 (00:01:00)** 62:25 With regards to the Bard filter, 63:1 would I have used a different device if I knew at 63:2 the time that the Bard filter was not ideal or as 63:3 good as some of the other implants? The answer 63:4 would have to be yes. 63:5 BY MR. MATTHEWS: 63:6 Q. You would have used -- 63:7 A. I would have used a different filter 63:8 if there was a different filter that I knew of that 63:9 was better, in terms of its safety profile. 63:10 Q. In terms of the documents that you 63:11 have, I think they are Exhibit-2 and 3, the health 63:12 hazard report and then the investigation conducted	03_20_18 combo final3_1.51

Page/Line	Source	ID
	63:13 by Bard that showed a fivefold increased risk for 63:14 fracture and embolization of that fracture, and you 63:15 told us that would be the type of information you 63:16 would want to know in your benefit/risk analysis, 63:17 knowing that -- 63:18 A. Yes. 63:19 Q. -- and seeing that today, would that 63:20 have been enough to use another filter?	
63:22 - 64:2	**D, ayala 03-21-2017 (00:00:17)** 63:22 THE WITNESS: Difficult to say with 63:23 certainty. It would depend upon what other filters 63:24 we had at the time and what their problems would 63:25 have been. But it would have been a very important 64:1 piece of information, as far as making decisions 64:2 regarding this or any other patient, yes.	03_20_18 combo final3_1.52
64:4 - 64:7	**D, ayala 03-21-2017 (00:00:04)** 64:4 Q. And it would have influenced your 64:5 prescribing habit? 64:6 *** 64:7 THE WITNESS: Yes.	03_20_18 combo final3_1.53
64:9 - 64:10	**D, ayala 03-21-2017 (00:00:06)** 64:9 Q. Let me show you a study, I'm going to 64:10 mark this as D'Ayala Exhibit Number 7. And this is	03_20_18 combo final3_1.54
66:19 - 67:8	**D, ayala 03-21-2017 (00:00:52)** 66:19 Q. The conclusion of this study 66:20 by Dr. Nicholson and other doctors in different 66:21 fields of medicine found the Bard Recovery and Bard 66:22 G2 filters had high prevalence of fracture and 66:23 embolization with potentially life-threatening 66:24 sequelae. 66:25 Doctor, if you had been warned prior 67:1 to June of 2007 of this information, I know this is 67:2 dated 2010, but I'm going to ask you the question 67:3 for purposes of a hypothetical, that is, had you 67:4 known this information of this conclusion, that the 67:5 G2 had a high prevalence of fracture and 67:6 embolization with life-threatening sequelae, would 67:7 that have influenced your prescribing habits and the 67:8 use of the G2 with Ms. Booker?	03_20_18 combo final3_1.55
67:10 - 67:10	**D, ayala 03-21-2017 (00:00:02)**	03_20_18 combo final3_1.56

Page/Line	Source	ID
	67:10 THE WITNESS: Yes.	
70:9 - 70:13	**D, ayala 03-21-2017 (00:00:19)**	03_20_18 combo final3_1.57
	70:9 Q. Well, let me ask you this question, 70:10 then, Doctor: If you knew back in 2007 when you 70:11 were implanting that filter that there was even a 12 70:12 percent probability of fracture with that filter, 70:13 would you have used a G2?	
70:15 - 70:20	**D, ayala 03-21-2017 (00:00:18)**	03_20_18 combo final3_1.58
	70:15 THE WITNESS: Unlikely. 70:16 BY MR. MATTHEWS: 70:17 Q. If there was a 25 percent risk of 70:18 filter fracture, can we safely say you would not 70:19 have used that filter? 70:20 A. Most likely.	
70:20 - 70:25	**D, ayala 03-21-2017 (00:00:16)**	03_20_18 combo final3_1.59
	70:20 A. But you have to 70:21 understand that you have to have a way of treating 70:22 these difficult patients. So some filter has to be 70:23 used. And it becomes a matter of deciding which 70:24 filter is best, so to speak. And sometimes that's 70:25 not entirely clear.	
73:1 - 73:3	**D, ayala 03-21-2017 (00:00:11)**	03_20_18 combo final3_1.60
	73:1 Q. Doctor, let me show you what has been 73:2 marked as Exhibit-11 to your deposition, which is an 73:3 internal document from Bard.	
73:19 - 74:1	**D, ayala 03-21-2017 (00:00:22)**	03_20_18 combo final3_1.61
	73:19 Q. First let me ask you, did you ever 73:20 use in your practice the Simon Nitinol filter, 73:21 referred here with an acronym SNF? 73:22 A. I have. 73:23 Q. And that is a filter, a permanent 73:24 filter that was in existence for many years prior to 73:25 the G2 being cleared by the FDA, correct? 74:1 A. Correct.	
77:14 - 77:17	**D, ayala 03-21-2017 (00:00:09)**	03_20_18 combo final3_1.62
	77:14 Q. Were the adverse events associated 77:15 with the nitinol filter or the G2 ever discussed 77:16 with you by any of the sales reps that called on 77:17 you?	
77:19 - 77:19	**D, ayala 03-21-2017 (00:00:02)**	03_20_18 combo final3_1.63

Page/Line	Source	ID
	126:16 Q. If you would have known there was up 126:17 to a 25 percent risk of filter fracture in that G2, 126:18 as we've seen in the articles in front of you, you 126:19 would have taken greater steps than what were taken 126:20 to make sure that filter was removed after implant 126:21 with that patient on that -- in that year, correct?	
126:23 - 127:11	**D, ayala 03-21-2017 (00:00:45)** 126:23 THE WITNESS: Knowing what I today, I 126:24 think it's safe to answer that question as yes. 126:25 Given the information we had at hand back then, I'm 127:1 not so sure anything would have changed. But, yes, 127:2 we make an effort to follow our patients back then 127:3 as now.	03_20_18 combo final3_1.98
	127:4 BY MR. MATTHEWS: 127:5 Q. Let me ask you about that, in terms 127:6 of the fracture rate. 127:7 Has Bard ever suggested a protocol 127:8 for your hospital, knowing what we know today, to 127:9 follow those patients that had Recovery and G2 127:10 filters to make sure that they are retrieved once 127:11 the risk of PE has subsided?	
127:13 - 127:13	**D, ayala 03-21-2017 (00:00:01)** 127:13 THE WITNESS: No.	03_20_18 combo final3_1.99
127:19 - 128:2	**D, ayala 03-21-2017 (00:00:17)** 127:19 Q. Doctor, the decision of whether or 127:20 how to treat a follow-up patient, you would agree 127:21 with me that's a medical decision, wouldn't you? 127:22 A. Yes. 127:23 Q. And it needs to be made by a medical 127:24 doctor with medical training? 127:25 A. Yes. 128:1 Q. And not by a device manufacturer? 128:2 A. Yes.	03_20_18 combo final3_1.100
10:12 - 10:17	**D, ayala 03-21-2017 (00:00:09)** 10:12 Doctor, could you state your name, 10:13 please? 10:14 A. Marcus D'Ayala. 10:15 Q. And what do you do, sir? 10:16 A. I'm a vascular surgeon in clinical 10:17 practice in Brooklyn, New York.	03_20_18 combo final3_1.101

EXHIBIT D

March 22, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 22, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 6 P.M.

(Pages 1210 through 1322)

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(Whereupon the video deposition of Guillermo Altonaga was played.) 03:11:58

MR. LOPEZ: Your Honor --

Please stop it.

I don't know that anyone could have heard that question. Would you mind if I read? It. It was the court reporter reading the question. 03:21:49

THE COURT: You can read the question and the answer.

MR. LOPEZ: Question: Would it be your expectation that when Bard launched a filter for commercial use that Bard would have an awareness about the long-term clinical performance of that device? 03:22:02

Answer: Yes.

(The video deposition of Mr. Altonaga continues to be played.) 03:22:39

MS. REED ZAID: The next witnesses appearing by videotape is Robert Ferrara. Robert Ferrara has a mechanical engineering degree from Polytechnic University and an M.B.A. from Dowling College. He was a sales representative at the GlaxoSmithKline from 2002 to 2004. He worked as a sales representative at C.R. Bard from 2004 to 2011 and during this time sold Bard's IVC filters. He currently works for Medtronic, another medical device manufacturer. 03:31:05

And, Your Honor, I would like to move into evidence Trial Exhibit 1103 (sic, corrected later in trial) which is 03:31:28

Designation Run Report

Altonaga 10-22-13 Booker Depo Designations Final2.1

Altonaga, Bill 10-22-2013

Plaintiffs Designations 00:13:20

Defense Designations 00:04:27

Their Conditionals 00:00:18

Total Time 00:18:05

Page/Line	Source	ID
	34:3 Q. What is that ultimate safety purpose? 34:4 A. To assure that the devices are as safe as they 34:5 possibly can be. 34:6 Q. What about from the standpoint of the public, 34:7 what is the underlying safety purpose behind postmarket 34:8 surveillance? 34:9 A. To make sure that the manufacturers are aware 34:10 of things that could harm people.	
71:24 - 72:5	**Altonaga, Bill 10-22-2013 (00:00:15)** 71:24 Q. All right. Are you familiar with the term 72:1 "misbranding"? 72:2 A. I am. 72:3 Q. What is it? 72:4 A. Misbranding means that you can mislead or 72:5 provide information that is false or misleading.	03_21_18 combo final2_1.5
72:11 - 73:23	**Altonaga, Bill 10-22-2013 (00:01:35)** 72:11 Q. In the context of promotional materials, does 72:12 misbranding apply to those types of materials, the 72:13 concept? 72:14 A. Yes, it could. 72:15 Q. Does misbranding apply to posters? 72:16 A. Yes, it could. 72:17 Q. Does it apply to tags? 72:18 A. Yes, it could. 72:19 Q. Does it apply to pamphlets? 72:20 A. Yes, it could. 72:21 Q. Circulars? 72:22 A. Yes, it could. 72:23 Q. Booklets? 72:24 A. Yes, it could. 73:1 Q. Brochures? 73:2 A. Yes, it could. 73:3 Q. Instruction books? 73:4 A. Yes, it could. 73:5 Q. Direction sheets? 73:6 A. Yes, it could. 73:7 Q. Information on a manufacturer's website? 73:8 A. Yes, it could. 73:9 Q. Okay. So if, for example, Bard, in any one of 73:10 those mediums, said that the failure rate, for example,	03_21_18 combo final2_1.6

Page/Line	Source	ID
	73:11 for migration of the Recovery filter is similar to 73:12 competitor filters and that wasn't true, would that be 73:13 an example of misbranding? 73:14 A. It could be. 73:15 Q. Could be or would be? 73:16 A. The way you posed the question, if it were 73:17 untrue? 73:18 Q. If it was false or misleading. 73:19 A. If it's unsubstantiated, then it would be false 73:20 or misleading. 73:21 Q. Well, when you say unsubstantiated -- 73:22 A. Meaning you don't have the facts to support 73:23 that particular claim.	
86:2 - 86:10	**Altonaga, Bill 10-22-2013 (00:00:27)** 86:2 Q. Do you agree that the performance failures of 86:3 marketed medical devices can pose serious risks to 86:4 public health? 86:5 A. Yes. 86:6 Q. Do you agree that recalls serve both to correct 86:7 defects in current and future devices and to notify 86:8 users of potential risks and steps to minimize the 86:9 impact of failure -- of device failure or malfunction? 86:10 A. Yes.	03_21_18 combo final2_1.7
87:2 - 87:4	**Altonaga, Bill 10-22-2013 (00:00:07)** 87:2 Q. Well, I mean, I'm asking you your 87:3 understanding. Would that include a medical device that 87:4 fails to perform as intended?	03_21_18 combo final2_1.8
87:6 - 87:6	**Altonaga, Bill 10-22-2013 (00:00:02)** 87:6 A. I would think that that is possible, yes.	03_21_18 combo final2_1.9
87:18 - 87:22	**Altonaga, Bill 10-22-2013 (00:00:19)** 87:18 Q. All right. In order to come to the conclusion 87:19 as to whether a device should or should not be recalled, 87:20 would it be important to consider the failure mode 87:21 evaluation and the severity of harm evaluation? 87:22 A. Yes.	03_21_18 combo final2_1.10
90:15 - 90:22	**Altonaga, Bill 10-22-2013 (00:00:23)** 90:15 Q. Can we agree, however, that the actual 90:16 universe of adverse reports or complications is 90:17 certainly going to be higher than what is actually 90:18 reported?	03_21_18 combo final2_1.11

Page/Line	Source	ID
136:7 - 136:18	**Altonaga, Bill 10-22-2013 (00:00:35)** 136:7 Q. So you do acknowledge that one of 136:8 the problems with fracture can involve the embolization 136:9 of that fracture fragment to other parts of the body? 136:10 A. I am, yes. 136:11 Q. All right. And give us some idea as to the 136:12 organs and parts of the body that a fracture can 136:13 embolize to. 136:14 A. I would say that the most likely place for it 136:15 to fracture would be up through the vena cava into the 136:16 right atrium. Its resting location could be the right 136:17 atrium, it could go into the left ventricle, or it could 136:18 end up in pulmonary circulation.	03_21_18 combo final2_1.17
142:10 - 142:17	**Altonaga, Bill 10-22-2013 (00:00:31)** 142:10 Q. And as a medical doctor, do you acknowledge 142:11 that the vena cava can actually expand by as much up to 142:12 50 percent its resting size? 142:13 A. I believe that that's true. 142:14 Q. Okay. As an example, if an individual has a 142:15 28-millimeter vena cava, given the various dynamics, 142:16 that could actually expand up to 42 millimeters, agreed? 142:17 A. Agreed.	03_21_18 combo final2_1.18
149:16 - 150:1	**Altonaga, Bill 10-22-2013 (00:00:27)** 149:16 Q. All right. And -- so just simply to throw out 149:17 the idea that filters are known to migrate, perforate, 149:18 or fracture, that sort of begs the question, does it 149:19 not, because you have to have an understanding of the 149:20 rate at which that occurs in order to know whether your 149:21 complication rate is either acceptable or not 149:22 acceptable? 149:23 A. Okay. 149:24 Q. Do you agree? 150:1 A. I don't disagree with that.	03_21_18 combo final2_1.19
152:6 - 152:10	**Altonaga, Bill 10-22-2013 (00:00:10)** 152:6 Q. Bard's required to be 152:7 transparent and upfront with all information, whether 152:8 it's good or bad? 152:9 A. I would think that they're required to do so, 152:10 yes.	03_21_18 combo final2_1.20
152:16 - 152:20	**Altonaga, Bill 10-22-2013 (00:00:18)**	03_21_18 combo final2_1.21

EXHIBIT E

March 22, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 22, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 6 P.M.

(Pages 1210 through 1322)

Official Court Reporter:
Elaine Cropper, RDR, CRR, CCP
Sandra Day O'Connor U.S. Courthouse
401 West Washington Street
Suite 312, SPC 35
Phoenix, Arizona 85003-2150
(602) 322-7245

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

Deposition Exhibit Number 3, and Trial Exhibit Number 905, Deposition Exhibit 19. 03:31:33

THE COURT: Any objection?

MS. HELM: No objection, Your Honor.

THE COURT: All right. Those are admitted. 03:31:45

(Exhibit Numbers 1130 and 905 were admitted into evidence.)

(Whereupon the video deposition of Robert Ferrara was played.)

MS. REED ZAID: Next witness appearing by videotape, which is only four minutes long, is Jason Greer. Jason Greer graduated from the University of Mississippi and became a sales representative at Bell South Mobility in 1991 and worked for two other companies doing sales until he joined Bard Peripheral Vascular in 1999 as a sales representative. In 2005 he became a district manager and throughout his time at Bard, he sold Bard's IVC filters. Mr. Greer left Bard in 2007 and currently works at another medical device manufacturer. 03:50:39 03:50:56

We would like to move one exhibit into evidence, Your Honor. It's Trial Exhibit 1912, Deposition Exhibit Number 7. 03:51:16

MS. HELM: Excuse me, Your Honor. No objection.

THE COURT: 1912 is admitted.

(Exhibit Number 1912 was admitted into evidence.)

MS. REED ZAID: Thank you.

Ladies and gentlemen, if you want to stand up while 03:51:45

Designation Run Report

Ferrara 04-07-17 Booker Depo Designations Final3

Ferrara, Robert 04-07-2017

Plaintiffs Designations 00:11:10

Plaintiffs Counters 00:00:49

Defense Designations 00:06:31

Total Time 00:18:30

Page/Line	Source	ID
	233:5 of discussing.	
233:12 - 233:17	**Ferrara, Robert 04-07-2017 (00:00:12)**	03_21_18 combo final3.49
	233:12 Q. Did you ever talk to Dr.	
	233:13 D'Ayala --	
	233:14 A. D'Ayala.	
	233:15 Q. D'Ayala about caudal migration	
	233:16 with the G2?	
	233:17 A. I couldn't say specifically.	
249:17 - 249:19	**Ferrara, Robert 04-07-2017 (00:00:07)**	03_21_18 combo final3.50
	249:17 Q. Were you aware while you were	
	249:18 working at Bard that the G2 had more	
	249:19 caudal migrations than the Recovery?	
249:22 - 250:8	**Ferrara, Robert 04-07-2017 (00:00:24)**	03_21_18 combo final3.51
	249:22 A. I wasn't privy to the numbers	
	249:23 for both of them. So I wouldn't be privy	
	249:24 to any of that.	
	250:1 Q. So, the same would be true about	
	250:2 the more tilting and more perforations?	
	250:3 A. Any tilting or any perforation	
	250:4 rate I would not have specific access to.	
	250:5 Q. All right. So I would take it	
	250:6 from this answer you would have not been	
	250:7 able to relay that information to Dr.	
	250:8 D'Ayala?	
250:15 - 250:17	**Ferrara, Robert 04-07-2017 (00:00:05)**	03_21_18 combo final3.52
	250:15 A. I could not have passed	
	250:16 to Dr. D'Ayala any information that I	
	250:17 didn't have or was approved to give him.	
250:22 - 251:21	**Ferrara, Robert 04-07-2017 (00:00:52)**	03_21_18 combo final3.53
	250:22 Q. Have you ever heard of the	
	250:23 migration push test?	
	250:24 A. No.	
	251:1 Q. Are you aware of any kind of	
	251:2 test done by Bard to determine how much	
	251:3 force any of its filters could endure	
	251:4 before they migrated?	
	251:5 A. Anecdotally I may have heard	
	251:6 that they did some type of testing, but I	
	251:7 couldn't tell you any specifics.	
	251:8 Q. Were you ever given any	

Page/Line	Source	ID
	251:9 information from that study that compared 251:10 the G2 to any other filters? 251:11 A. Which study? 251:12 Q. The migration push test? 251:13 A. No, I was not given any 251:14 information from any test. 251:15 Q. So again, if you didn't have 251:16 that information, you would not be able to 251:17 provide that information to any of the 251:18 physicians that you worked with? 251:19 A. Correct, I could not provide any 251:20 information I did not have or was approved 251:21 to give.	
283:8 - 283:13	**Ferrara, Robert 04-07-2017 (00:00:17)** 283:8 Q. All right. So, in terms of any 283:9 studies that Bard did comparing their 283:10 filter, either the Recovery or the G2, to 283:11 other filters, you don't think that they 283:12 had to -- the responsibility to share that 283:13 information?	03_21_18 combo final3.54
283:16 - 283:19	**Ferrara, Robert 04-07-2017 (00:00:07)** 283:16 A. I don't feel they had the 283:17 responsibility to share any information 283:18 that's not level 1A evidence, like a true 283:19 clinical trial.	03_21_18 combo final3.55
284:12 - 284:16	**Ferrara, Robert 04-07-2017 (00:00:18)** 284:12 Q. do you think it's being 284:13 honest not to tell her physician that the 284:14 filter that's about to be implanted into 284:15 her body has a greater propensity to tilt, 284:16 migrate, or penetrate than other filters?	03_21_18 combo final3.56
284:22 - 285:7	**Ferrara, Robert 04-07-2017 (00:00:33)** 284:22 I think that Dr. D'Ayala 284:23 specifically was made aware of the 284:24 potential complications of the IVC filter 285:1 and all IVC filters. You're describing 285:2 complications, known complications of an 285:3 IVC filter, and I don't believe there is 285:4 any level 1A evidence about any type of 285:5 comparison between that filter and any	03_21_18 combo final3.57

EXHIBIT F

March 22, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

_____

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 22, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 6 P.M.

(Pages 1210 through 1322)

Official Court Reporter:
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735, Deposition Exhibit 20; and Trial Exhibit 1949, Deposition Exhibit 21. I would like to move these into evidence at this time, Your Honor. 02:18:30

THE COURT: Any objection?

MS. HELM: No, Your Honor. 02:18:43

MS. REED ZAID: Thank you.

THE COURT: All right. Those exhibits are admitted. And you may play the deposition testimony.

(Exhibit Numbers 1948, 1950, 1951, 1940, 1941, 1944, 1945, 1946, 735, 1949 were admitted into evidence.) 02:18:48

(Whereupon the deposition of Gin Schulz was played.)

THE COURT: Counsel, can we turn down just a little bit?

Let's stop the video there.

All right. Members of the jury, we've reached 2:30. We will plan to resume at 2:45. We will excuse you at this time. 02:29:44

(Jury departs at 2:29.)

(Recess at 2:29; resumed at 2:46.)

(Jury enters at 2:46.) 02:46:33

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated.

Counsel, you may continue with the deposition.

(The deposition of Gin Schulz continues to be played.) 02:47:20

Designation Run Report

Schultz 01-30-14 Booker Depo Designations Final 4

Shultz, Gin 01-30-2014

Plaintiffs Designations 00:23:22

Defense Designations 00:09:30

Total Time 00:32:52

Page/Line	Source	ID
	125:15 which one to use or not use, right?	
126:1 - 126:12	**Shultz, Gin 01-30-2014 (00:00:30)** 126:1 when we 126:2 have a clinical study, which is 126:3 prospective and you have good 126:4 comparison data, then that's the 126:5 type of information that you can 126:6 put into your labeling or 126:7 disclose, because then it's -- 126:8 it's very clear what the data is 126:9 telling you. 126:10 So we have put that into our 126:11 labeling when we've had clinical 126:12 data.	03_21_18 Combo Final4.15
139:14 - 139:17	**Shultz, Gin 01-30-2014 (00:00:07)** 139:14 In claiming a device as 139:15 predicate, Bard is claiming that the 139:16 Recovery filter is substantially similar 139:17 to the Simon Nitinol filter, isn't it?	03_21_18 Combo Final4.16
139:20 - 139:24	**Shultz, Gin 01-30-2014 (00:00:06)** 139:20 THE WITNESS: It's similar 139:21 in the function of the device. 139:22 It's similar in the safety and 139:23 efficacy. It's safety -- it's 139:24 similar in the technology.	03_21_18 Combo Final4.17
140:5 - 140:10	**Shultz, Gin 01-30-2014 (00:00:13)** 140:5 So as physicians who 140:6 previously used the Simon Nitinol filter 140:7 and now Bard is marketing the Recovery 140:8 filter, the presumption was the devices 140:9 had equivalent safety, right? 140:10 A. Yes.	03_21_18 Combo Final4.18
168:8 - 168:10	**Shultz, Gin 01-30-2014 (00:00:06)** 168:8 Q. Do you agree that an 168:9 adulterated product is one that fails to 168:10 meet its minimum safety specifications?	03_21_18 Combo Final4.19
168:13 - 168:16	**Shultz, Gin 01-30-2014 (00:00:04)** 168:13 THE WITNESS: It's -- 168:14 adulterated product would be 168:15 product that doesn't meet its	03_21_18 Combo Final4.20

Page/Line	Source	ID
	168:16 specification period.	
168:18 - 169:8	**Shultz, Gin 01-30-2014 (00:00:30)** 168:18 Q. Okay. And -- 168:19 A. Of any sort. 168:20 Q. In this case, for the 168:21 filters, that would be migration 168:22 resistance specifications? 168:23 A. The -- 168:24 Q. Among others? 169:1 A. It would be -- on 169:2 adulteration, it would be specifications 169:3 of the device. So there's not a release 169:4 test for releasing a batch from migration 169:5 resistance. 169:6 So the migration resistance 169:7 wouldn't be a specification on the 169:8 device.	03_21_18 Combo Final4.21
175:2 - 175:9	**Shultz, Gin 01-30-2014 (00:00:11)** 175:2 Q. Okay. So you have product 175:3 performance specifications that will lay 175:4 out what the specifications are? 175:5 A. Correct. 175:6 Q. Okay. So if the product 175:7 isn't meeting those specifications, then 175:8 it's adulterated? 175:9 A. Correct.	03_21_18 Combo Final4.22
177:5 - 178:1	**Shultz, Gin 01-30-2014 (00:00:28)** 177:5 Q. Okay. So as far as if 177:6 you become -- if Bard becomes concerned 177:7 about safety problems with the device -- 177:8 A. Yes. 177:9 Q. -- and they want to get that 177:10 information out, there are measures Bard 177:11 can take? 177:12 A. Yes. 177:13 Q. Such as, they can do a field 177:14 correction, right? 177:15 A. Yes. 177:16 Q. They can do a medical device 177:17 notification, right?	03_21_18 Combo Final4.23

EXHIBIT G

March 22, 2018 P.M.

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 22, 2018 1:00 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 6 P.M.

(Pages 1210 through 1322)

Official Court Reporter:
Elaine Cropper, RDR, CRR, CCP
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we start this, go head. We've got 25 minutes to go and if you need to stretch, feel free and if you don't, that's okay, too. 03:51:48

(Whereupon the video deposition of Jason Greer was played.)

MS. REED ZAID: The next witness to appear by videotape is Christopher Ganser. Christopher Ganser is a graduate of the California State University in Long Beach. He earned a bachelor of science in industrial technology and quality assurance. 03:56:53

He began his career with C.R. Bard in 1994 and worked in Quality Assurance. Mr. Ganser was Vice President, Regulatory Science, at C.R. Bard from 2005 through 2006 and Vice President, Quality Environmental Services and Safety, from 2007 through 2011 when he left Bard. 03:57:05

Mr. Ganser currently runs his own consulting firm and consults with medical device manufacturing. 03:57:27

There's one exhibit we would like to move into evidence Your Honor. It's Trial Exhibit 4328, Deposition Exhibit 517.

MS. HELM: No objection, Your Honor. 03:57:47

MS. REED ZAID: And the tape is 16 minutes.

THE COURT: It is admitted.

(Exhibit Number 4328 was admitted into evidence.)

(Whereupon the video deposition of Christopher Ganser was played.) 04:01:47

Designation Run Report

Ganser 10-11-16 Booker Depo Designations Final 2.1

Ganser, Christopher 10-11-2016

Plaintiffs Designations	00:09:39
Defense Designations	00:00:06
Plaintiffs Counters	00:00:14
Defense Designations	00:06:24
Total Time	**00:16:23**

Page/Line	Source	ID
6:24 - 7:2	**Ganser, Christopher 10-11-2016 (00:00:03)** 6:24 Q. State your full name, please, for the 7:1 record. 7:2 A. Christopher David Ganser.	3_21_18 combo Final2_1.1
44:13 - 44:18	**Ganser, Christopher 10-11-2016 (00:00:14)** 44:13 Q. I keep hearing that one of the benefits 44:14 was -- I mean, these weren't being put in patients for 44:15 the folly of just taking them out, right? That wasn't 44:16 the purpose of putting them in, just to put them in and 44:17 let's see if we can take them out later. I'm not being 44:18 facetious about that.	3_21_18 combo Final2_1.5
44:18 - 44:23	**Ganser, Christopher 10-11-2016 (00:00:14)** 44:18 That wasn't the purpose for 44:19 these things being implanted, true? 44:20 A. The purpose was, as we have agreed, was 44:21 to, you know, trap clot burden, lyse the clot burden, 44:22 prevent that clot from migrating to the heart. That 44:23 was the purpose of the filter.	3_21_18 combo Final2_1.6
46:1 - 46:5	**Ganser, Christopher 10-11-2016 (00:00:11)** 46:1 Q. And do you agree that the consequence of 46:2 a product being adulterated is that it may not be 46:3 marketed until and unless it's adulterated quality is 46:4 rectified? 46:5 A. Yes.	3_21_18 combo Final2_1.7
49:6 - 49:8	**Ganser, Christopher 10-11-2016 (00:00:03)** 49:6 Q. And you agree that the company is 49:7 required to follow this law? 49:8 A. Yes.	3_21_18 combo Final2_1.8
50:11 - 50:24	**Ganser, Christopher 10-11-2016 (00:00:40)** 50:11 Sir, on the issue of the substantial 50:12 equivalence, do you agree that a manufacturer who 50:13 submits a 510(k) application must assure that any 50:14 device submitted under the 510(k) route be as safe and 50:15 effective as its predicate device and not raise new 50:16 questions about safety or effectiveness? 50:17 A. I believe that's a requirement. 50:18 Q. And that should maintain itself 50:19 throughout the life of the product, right, not just for 50:20 purposes of getting clearance. It should maintain that 50:21 quality throughout the life of the device that got	3_21_18 combo Final2_1.9

Page/Line	Source	ID
	50:22 cleared through the 510(k); wouldn't you agree with 50:23 that? 50:24 A. Yes.	
51:1 - 51:4	**Ganser, Christopher 10-11-2016 (00:00:10)** 51:1 Q. Because to get 510(k) clearances, you 51:2 don't have to do a clinical trial, right? 51:3 A. It depends upon the device and what the 51:4 FDA requirements are.	3_21_18 combo Final2_1.10
53:8 - 54:1	**Ganser, Christopher 10-11-2016 (00:01:01)** 53:8 Q. And in the instance of the Recovery 53:9 filter, the bench testing was represented to FDA as 53:10 being -- the results being that it was equivalent for 53:11 migration to the Simon Nitinol filter? 53:12 A. Again, without looking at the 510(k), I 53:13 can't say that specifically. I would assume it did. 53:14 Q. I mean, you would have had to, or you 53:15 wouldn't have got 510(k) clearance? 53:16 A. Right. 53:17 Q. But you and I agree that the bench 53:18 testing is not the be all, end all. You've now got to 53:19 see whether or not the bench testing plays itself out 53:20 in the real clinical world once it gets implanted in 53:21 patients, right? 53:22 A. You have to -- you have to monitor the 53:23 product and as part of a postmarketing surveillance 53:24 process and make a determination is the product as good 54:1 as what you tried to determine on the bench.	3_21_18 combo Final2_1.12
54:2 - 54:14	**Ganser, Christopher 10-11-2016 (00:00:25)** 54:2 Q. And on the bench it seemed that the 54:3 Recovery filter was just as good as the Simon Nitinol 54:4 filter when it came to migration resistance, right? 54:5 A. Again, without having the data in front 54:6 of me to look at, it seems just as good. That's kind 54:7 of a vague term. 54:8 Q. Well, how about substantially 54:9 equivalent? 54:10 A. Substantially equivalent, again, we 54:11 wouldn't have gotten the indication if it wasn't. 54:12 Q. Right, and it didn't raise new issues of 54:13 safety and effectiveness?	3_21_18 combo Final2_1.13

EXHIBIT H

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 16, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 3 P.M. SESSION

(Pages 580 - 654)

Official Court Reporter:
Patricia Lyons, RMR, CRR
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14:27:45 A Yes.
Q To stop?
A Yes.
MR. O'CONNOR: No further questions.
14:27:53 THE COURT: What did you say, Mr. O'Connor?
MR. O'CONNOR: Excuse me?
THE COURT: I didn't hear what you said.
MR. O'CONNOR: I said I have no more questions. Thank you, Your Honor.
14:28:00 THE COURT: All right.
We're going to take a break, ladies and gentlemen. We'll resume at a quarter to.
You can step down, sir.
(The jury exited the courtroom at 2:28.)
14:28:37 THE COURT: All right. We'll take a break for 15 minutes. Thank you.
(Recess taken from 2:28 to 2:45. Proceedings resumed in open court with the jury present.)
THE COURT: Thank you, please be seated.
14:45:59 Counsel, your next witness.
MR. LOPEZ: Yes, Your Honor. May I approach the podium?
At this time plaintiffs are going to call by videotape deposition Natalie Wong, who is currently employed
14:46:18 at Bard Peripheral Vascular and since 2008 has been a quality

14:49:35 trial exhibits into evidence, Your Honor.

MS. HELM: No objection, Your Honor.

THE COURT: All right, those will all be admitted into evidence.

14:49:44 MR. LOPEZ: And allowed to be displayed on the video?

THE COURT: Yes.

MR. LOPEZ: Thank you.

(Exhibits 2243, 2244, 2057, 2245, 2246, 2247, 2248, 2249, 2250, 2052, 2251, and 2253 admitted.)

14:49:50 (Video deposition played.)

MR. LOPEZ: That concludes her testimony, Your Honor.

THE COURT: All right.

MR. LOPEZ: We have another deposition to play, Your Honor. We won't get through it, but we'll get started.

16:11:36 THE COURT: Okay.

We'll go to 4:30, ladies and gentlemen, then break.

MR. LOPEZ: This is the deposition of Janet Hudnall.

Janet Hudnall has a degree in industrial engineering from the Georgia Institute of Technology, and an MBA from ASU.

16:11:52 She began working for what became Bard Peripheral Vascular in June 1998 as a product development engineer and was promoted so senior product manager in 2002 and marketing manager in 2004.

As marketing manager, Ms. Hudnall managed marketing

16:12:09 activities of BPV's IVC filter product line and was involved

Designation Run Report

Wong 10-18-16 Booker Depo Designations final3

Wong, Natalie 10-18-2016

Plaintiffs Designations 01:03:46

Defense Designations 00:13:03

Pliaintiffs and Defense Designations 00:03:51

Total Time 01:20:40

Page/Line	Source	ID
	29:19 understands? 29:20 A. So something that happens, you know, if a 29:21 product -- you know, if something didn't work 29:22 correctly, as the physician intended. 29:23 Q. Okay. Or as the manufacturer intended. 29:24 Right? 29:25 A. Or the manufacturer intended, yes.	
32:13 - 32:16	**Wong, Natalie 10-18-2016 (00:00:07)** 32:13 Q. why does Bard do root cause 32:14 analysis, I mean, what's their -- why do they do 32:15 them? 32:16 A. To prevent failure modes from occurring.	03_16_18 Combo final3.22
32:17 - 32:19	**Wong, Natalie 10-18-2016 (00:00:05)** 32:17 Q. And is that something that's important to 32:18 do? 32:19 A. Yes, absolutely.	03_16_18 Combo final3.23
32:20 - 32:22	**Wong, Natalie 10-18-2016 (00:00:04)** 32:20 Q. why is it important? 32:21 A. Because we don't want complaints. We don't 32:22 want patient injury.	03_16_18 Combo final3.24
32:23 - 33:20	**Wong, Natalie 10-18-2016 (00:00:49)** 32:23 Q. It's important to understand the root cause 32:24 of failure modes to prevent injury to patients. 32:25 Fair? 33:1 A. Yes. 33:2 Q. And safety of the patients is first and 33:3 foremost for manufacturing companies. Right? 33:4 A. Yes. 33:5 Q. And -- and Bard feels that way? 33:6 A. Yes. 33:7 Q. So as of today, has Bard determined the 33:8 root cause of filter fracture? 33:9 A. I don't know. I haven't been on filters 33:10 the last several years. 33:11 Q. As of the time you left filters in -- in 33:12 2012, has Bard figured out the root cause of filter 33:13 fracture? 33:14 A. No, not that I know of. 33:15 Q. How about filter migration? 33:16 A. No, not that I know of.	03_16_18 Combo final3.25

Page/Line	Source	ID
	33:17 Q. How about perforations? 33:18 A. Not that I know of. 33:19 Q. How about tilt? 33:20 A. Not that I know of, no.	
34:1 - 34:6	**Wong, Natalie 10-18-2016 (00:00:15)** 34:1 Q. Bard continues to sell, despite not having 34:2 identified a root cause of -- of the failures of -- 34:3 of its failure modes, its IVC filters for placement 34:4 in veins in patients -- in a vein that leads directly 34:5 to the heart and lungs? 34:6 A. Yes.	03_16_18 Combo final3.26
34:20 - 34:24	**Wong, Natalie 10-18-2016 (00:00:15)** 34:20 Q. Do you think that the fact that Bard has 34:21 not now, in 12 years of selling its filters, been 34:22 able to identify the root cause of the failure modes 34:23 associated with those filters, is something a 34:24 physician would want to know?	03_16_18 Combo final3.27
35:6 - 35:20	**Wong, Natalie 10-18-2016 (00:00:30)** 35:6 Yeah, I think physicians should know, and I 35:7 think we do communicate through the IFU. 35:8 BY MR. DEGREEFF: 35:9 Q. So you believe that in the IFU it states 35:10 that Bard has failed to identify the root cause of 35:11 the failure modes? 35:12 A. Sorry, no, not that part. 35:13 Q. Okay. As far as you know, has it ever been 35:14 communicated to physicians that Bard has been unable 35:15 to identify the root cause of the failure modes 35:16 associated with its filters? 35:17 A. I don't know what's been communicated. 35:18 Q. As you sit here, are you aware of that 35:19 occurring? 35:20 A. No.	03_16_18 Combo final3.28
39:15 - 39:17	**Wong, Natalie 10-18-2016 (00:00:03)** 39:15 were you tracking and trending complaints and 39:16 adverse events? 39:17 A. Yes.	03_16_18 Combo final3.29
40:7 - 40:10	**Wong, Natalie 10-18-2016 (00:00:12)** 40:7 Q. As a quality engineering manager, did 40:8 you -- did you from -- well, were you involved with	03_16_18 Combo final3.30

Page/Line	Source	ID
	142:2 A. Yes. 142:3 Q. And you were actually the lead investigator 142:4 on the G2 caudal migration failure investigations 142:5 report. Right? 142:6 A. Yes. With the support of my team.	
145:19 - 146:20	**Wong, Natalie 10-18-2016 (00:01:40)** 145:19 Q. And now look at the next page, if you 145:20 would. Here we've got "G2 Compared to SNF and RNF," 145:21 is the heading. Right? 145:22 A. Yes. 145:23 Q. It says as of 2/28/06, SNF had zero caudal 145:24 migrations reported out of 34,000 sales. Right? 145:25 A. Yes. 146:1 Q. And the RNF had three caudal migrations 146:2 reported out of 25,000 sales, right, for a caudal 146:3 migration rate of .01? 146:4 A. Yes. 146:5 Q. And do we know what the rate for the SNF 146:6 was? I think if you look on page -- 146:7 A. SNF is zero. 146:8 Q. Or, excuse me, do we know what the rate for 146:9 the G2 was? 146:10 A. .15 percent. 146:11 Q. And that was -- that was 13 migrations in 146:12 only 8,900 sold? 146:13 A. 13 migrations in 8,924 sold, yes. 146:14 Q. And fair to say that the Recovery is more 146:15 resistant to caudal migration than the G2? 146:16 A. Yeah, I don't think we had that many 146:17 reports of caudal migration with Recovery. 146:18 Q. And the SNF is, given that it had zero 146:19 caudal migrations reported, it's certainly more 146:20 resistant to caudal migration than the G2. Correct?	03_16_18 Combo final3.109 WONG 543.8 WONG 543.8.1 WONG 543.8.2 clear
146:22 - 146:23	**Wong, Natalie 10-18-2016 (00:00:03)** 146:22 THE WITNESS: Yes, there were no caudal 146:23 migrations of the SNF.	03_16_18 Combo final3.110
147:22 - 148:10	**Wong, Natalie 10-18-2016 (00:00:46)** 147:22 Based on the actual real-life data that was 147:23 available versus hypothetical world, the -- the G2 147:24 was less -- the -- excuse me, the SNF was better than	03_16_18 Combo final3.111

Page/Line	Source	ID
	147:25 the G2 with regards to caudal migration?	
	148:1 MS. DALY: He's talking about based on your	
	148:2 data here.	
	148:3 THE WITNESS: That SNF -- sorry, SNF is	
	148:4 better than G2 on caudal migration, yes.	
	148:5 BY MR. DEGREEFF:	
	148:6 Q. And it would be -- based on the data	
	148:7 that's -- the available data that's in this	
	148:8 spreadsheet, it would be inaccurate to say that the	
	148:9 G2 was more stable than the -- than the RNF.	
	148:10 Correct?	
148:12 - 148:12	**Wong, Natalie 10-18-2016 (00:00:05)**	03_16_18 Combo final3.112
	148:12 THE WITNESS: Yes.	
151:19 - 152:9	**Wong, Natalie 10-18-2016 (00:00:50)**	03_16_18 Combo final3.113
	151:19 Q. Okay. Look at the next page, if you would.	WONG 543.16
	151:20 This is the caudal severity description. And I'm	
	151:21 looking at type III and type IV. Caudal migration	WONG 543.16.2
	151:22 can be -- can result in a reintervention to remove	
	151:23 the filter. Right?	
	151:24 A. Yes, for -- for the type III.	
	151:25 Q. And, yeah, and caudal migration can result	
	152:1 in the need to repair damage to a patient's anatomy?	WONG 543.16.3
	152:2 A. Yes.	
	152:3 Q. And caudal migration can result in patient	WONG 543.16.4
	152:4 injury?	
	152:5 A. Yes.	
	152:6 Q. And caudal migration can result in a filter	WONG 543.16.6
	152:7 no longer providing its primary function of -- of	
	152:8 protection from pulmonary embolism?	
	152:9 A. Yes.	
152:25 - 156:3	**Wong, Natalie 10-18-2016 (00:04:22)**	03_16_18 Combo final3.114
	152:25 And caudal migration can also result in	WONG 543.16.7
	153:1 excessive tilt; is that right?	
	153:2 A. Yes.	
	153:3 Q. And it can also result in an arm and leg --	
	153:4 an arm or leg in a side branch of the vena cava?	
	153:5 A. Yes.	
	153:6 Q. And caudal migration can also result in	
	153:7 iliac or renal confluence?	
	153:8 A. I think here it's saying it could be in --	

Page/Line	Source	ID
	184:20 Q. And this was -- this increased rate of 184:21 caudal migration with the G2 versus the RNF is 184:22 consistent with everything we looked at in your 2006 184:23 PowerPoints also. Right? 184:24 A. Yes, G2 had more caudal than RNF, yes. 184:25 Q. And caudal migration is an aspect of 185:1 stability of the filter. Fair? 185:2 A. Yes. 185:3 Q. So would it be inaccurate to say that the 185:4 G2 had increased stability over the Recovery? 185:5 A. I don't know.	clear
185:6 - 186:7	**Wong, Natalie 10-18-2016 (00:01:27)** 185:6 Q. Well, certainly, with regard to caudal 185:7 migration, it lacks stability in comparison to the 185:8 Recovery. Correct? 185:9 A. In the caudal migration direction. 185:10 Q. Okay. Well, look at the next one down, 185:11 cephalad migration, that's -- that's towards the 185:12 head. Correct? 185:13 A. Yes. 185:14 Q. And you've got the G2 and the RNF both have 185:15 4 percent migration rate, right, cephalad migration 185:16 rate? 185:17 A. Yes. 185:18 Q. And the comment is "same." Correct? 185:19 A. Yes, I'm just confused, though, with this 185:20 chart. 185:21 Q. Well, so you're looking at -- you've got 185:22 the G2 has a higher rate of migration, of caudal 185:23 migration rate than the RNF. Right? 185:24 A. Yes, but I think it might be relative to 185:25 filter fracture. 186:1 Q. Well, there's -- there's a separate line 186:2 item in here that deals with limb detachments. 186:3 Right? 186:4 A. Yes, but this packet is for G2 and G2X 186:5 fracture analysis. So I think these are fractures. 186:6 And of those fractures, how many were caudal 186:7 migration in association with the fracture.	03_16_18 Combo final3.144 WONG 546.18.2 clear
186:8 - 186:15	**Wong, Natalie 10-18-2016 (00:00:26)**	03_16_18 Combo final3.145

EXHIBIT I
(Filed Under Seal)

EXHIBIT J

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 21, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 5 A.M. SESSION

(Pages 900 - 950)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

09:33:11 MS. REED ZAIC: Yes, Your Honor.
THE COURT: Is there any objection?
MS. HELM: No, Your Honor.
THE COURT: All right, those exhibits are admitted.
09:33:20 (Exhibits 2368, 2349, 1811, 2355, 1806, 1807 admitted.)
(Video testimony played.)
MS. REED ZAIC: Apologize, Your Honor. I believe my co-counsel took the summary out the door.
THE COURT: Ladies and gentlemen, if you want to
10:13:45 stand up for a minute, feel free, while we're finding the documents.
MS. REED ZAIC: The next --
THE COURT: All right. Thanks.
MS. REED ZAIC: The next witness will be by video.
10:14:16 It is Dr. Brandon Kang. He's a board certified radiologist and diagnostic radiologist. He is chief of radiology and director of interventional radiology at North Metropolitan Radiology Associates in Georgia.
Dr. Kang graduated from the University of Tennessee
10:14:32 Medical School in 1999 and completed a fellowship at Emory University Hospital in 2005.
(Video testimony played.)
THE COURT: Counsel, let's stop the video, please.
We'll take our morning break, ladies and gentlemen,
10:30:04 and resume at 9:45.

Kang 06-15-17 Booker Depo Designations FINAL5

Kang, Brandon 06-15-2017

Plaintiffs Designations 00:17:47

Defense Designations 00:14:40

Plaintiffs And Defense Designations 00:01:18

Total Time 00:33:45

Page/Line	Source	ID
	47:18 A. Yes.	
54:16 - 54:19	**Kang, Brandon 06-15-2017 (00:00:10)**	03_20_18 combo FINAL5.53
	54:16 Q. Were you ever told by Bard when you were 54:17 using the Bard filters that there were no randomized 54:18 control trials showing the decrease in mortality with 54:19 use of Bard filter?	
54:21 - 54:21	**Kang, Brandon 06-15-2017 (00:00:01)**	03_20_18 combo FINAL5.54
	54:21 A. No.	
55:9 - 55:10	**Kang, Brandon 06-15-2017 (00:00:06)**	03_20_18 combo FINAL5.55
	55:9 Q. Were you ever warned by Bard that there was a 55:10 fracture rate of over 10 percent with the G2 filter?	
55:12 - 55:15	**Kang, Brandon 06-15-2017 (00:00:09)**	03_20_18 combo FINAL5.56
	55:12 A. No. 55:13 Q. If you had been so warned by Bard, would you 55:14 have used it in your patients? 55:15 A. No.	
55:16 - 55:17	**Kang, Brandon 06-15-2017 (00:00:08)**	03_20_18 combo FINAL5.57
	55:16 Q. If fracture was prevalent with the G2 filter, 55:17 should doctors and patients be told this?	
55:19 - 56:1	**Kang, Brandon 06-15-2017 (00:00:24)**	03_20_18 combo FINAL5.58
	55:19 Q. Would you expect this to be warned about by 55:20 Bard? 55:21 A. Yes, I would expect that. 55:22 Q. Did Bard ever warn you of that? 55:23 A. No. 55:24 Q. Did Bard ever warn you about the rate of 55:25 caudal migration of the Bard filter? 56:1 A. No.	
59:1 - 59:2	**Kang, Brandon 06-15-2017 (00:00:06)**	03_20_18 combo FINAL5.59
	59:1 Q. Based upon your contact with Ms. Booker, 59:2 would you describe her as a compliant patient?	
59:4 - 59:9	**Kang, Brandon 06-15-2017 (00:00:22)**	03_20_18 combo FINAL5.60
	59:4 A. Yes. 59:5 Q. I think I forgot to ask you at the very 59:6 beginning, are you board certified? 59:7 A. Yes, I am. 59:8 Q. And by what board are you certified? 59:9 A. American Board of Radiology.	
60:4 - 60:12	**Kang, Brandon 06-15-2017 (00:00:25)**	03_20_18 combo FINAL5.61
	60:4 Prior to your deposition today, did you have	

EXHIBIT K
(Filed Under Seal)

EXHIBIT L
(Filed Under Seal)

EXHIBIT M
(Filed Under Seal)

EXHIBIT N
(Filed Under Seal)

EXHIBIT O
(Filed Under Seal)

EXHIBIT P
(Filed Under Seal)

EXHIBIT Q
(Filed Under Seal)

EXHIBIT R

Lehmann Thomas, LLC

Memo

To: Doug Uelmen, BPV

From: John Lehmann, MD

Cc: Brian Barry, Corporate
Paul Kowalczyk, Corporate
Chris Ganser, Corporate

Date: April 27, 2004

Re: Recovery Filter Migration HHE

Doug, here's the completed Health Hazard Evaluation.

Regards, John W Lehmann MD

Summary of Health Hazard Evaluation: A case of vena cava filter migration associated with patient death was reported after the successful implantation of a Bard Recovery® Nitinol Vena Cava Filter. Evaluation demonstrated an intact filter and a large thromboembolus, with clot and filter lodging in the right ventricle resulting in cardiac perforation and tamponade.

Conclusion: Vena cava filter migrations are a recognized and accepted complication of this type of therapy. Such complications may be serious and can occasionally be fatal. The evidence to date does not demonstrate that these types of events are occurring with excess frequency with the Bard Recovery® Nitinol Vena Cava Filter.

Description of the problem: A complaint in April, 2004 regarding a Bard Recovery® Nitinol Vena Cava Filter (Recovery VC Filter) migration associated with a patient death led to a review of the potential health hazard associated with such occurrences.

Actual occurrence of injuries: The complaint involved a 55 year old female patient admitted to the hospital in March, 2004 with subarrachnoid hemorrhage, who was found to have DVT during her hospitalization. Because of her recent intracranial hemorrhage, she was not a candidate for anticoagulation, and a Recovery VC Filter was placed on 3/31/04 in an approximately 25 mm diameter vena cava. The Recovery VC Filter was deployed approximately 1 cm below the lower renal vein, with normal placement found on post procedural vena cavagrams. The patient was discharged from the hospital on 4/1/04 to home; and was found dead in bed on 4/13/04.

Post mortem examination determined that the cause of death was cardiac rupture, with puncture of the right ventricle by inferior vena cava filter. The death certificate is said to describe an “inferior vena cava filter placed for DVT’s dislodged by thrombus and migrated to the heart.”

Inspection of the thrombus / filter mass on 4/19/04 revealed dimensions of 2.5 cm in diameter and 4.5 cm in length (which was slightly smaller than the dimensions noted immediately post mortem). The thrombus / filter mass was attached to the right ventricular wall. X-rays confirmed that all filter arms, legs and hooks were present, even though some of the hooks and legs were contained within the thrombus. The thrombus was determined to be ante mortem. The vena cava was estimated to have an internal diameter of 30 – 35 mm, but was otherwise unremarkable. Small pulmonary emboli were found in the lungs.

Human exposure to the problem: Embolism of vena cava filters is a generic and well recognized risk of this technology. Events have been reported in the medical literature since the early 1980s as well as in the MAUDE database; these reports include migrations to the heart and include fatal outcomes.

Male and female patients at risk of pulmonary embolism who are either unable to take anticoagulants, are anticoagulant failures, or who are at unusually high risk are generally indicated for the use of vena cava filters in general and the Recovery VC Filter in specific.

General consequences: Migration of vena cava filters can have minimal consequences in some patients. In others it results in damage to the vena cava or obstruction of the renal veins. If the device and associated thrombus migrates into the heart this can lead to direct impairment of cardiac function including valvular dysfunction, reduced cardiac output, perforation with tamponade, circulatory collapse and death.

Other recognized causes of mortality associated with vena cava filters are vena caval obstruction, vena caval perforation with damage to adjacent structures, and filter failure resulting in release of thrombus leading to pulmonary embolism.

Population exposed to risk: Generally adult patients with a high risk for pulmonary embolic disease.

Mitigating/predisposing factors in population at risk: Mitigating factors include the close medical attention such patients generally receive. Predisposing factors in this population include coagulation abnormalities, obesity, sleep apnea syndrome, perioperative condition, congestive heart failure, cardiac arrhythmia, prolonged immobility and anticoagulant intolerance / failure.

Nature and seriousness of the risk: The nature of the risk ranges from minimal (asymptomatic migration without sequelae) to catastrophic (acute circulatory impairment from pulmonary or cardiac embolization with clot, filter or both). The latter risk is serious and potentially fatal.

Likelihood of occurrence of problem: Considering the problem to be vena cava filter migration into or near to the heart, there have been 4 such migrations of the Recovery VC Filter, with two fatalities, in an estimated 8,200 sales through mid-April, 2004, for a rate of 0.05%. One instance was a deployment error, and the other three occurred after apparently normal deployments on Days 6, 13 and 14.

Considering the problem to be death in association with vena cava filter use (resulting from one of the four major known complications: migration, caval obstruction, caval perforation and pulmonary embolus / acute respiratory distress), there have been 3 deaths associated with the Recovery VC Filter, 2 from filter migration related to large thromboembolic load and one from a pulmonary embolus, for a rate of 0.037%.

These types of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature. Comparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates for a number of reasons:

- Potential under-reporting
- Inadequate description of events in the MAUDE database, resulting in potential misclassification
- Very low frequency of observed events
- Sales data can only be roughly estimated
- High variability in event rates across devices and across time periods

However, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported, as well as fatalities from the other known complications associated with the implantation of such devices.

Likelihood of harm if problem occurs: The likelihood of harm if the Recovery VC Filter migrates to or near the heart is significant, but unquantifiable.

Is product essential to health?: Yes, vena cava filters are essential to health for the indicated patients, who may have no other alternative to prevent pulmonary embolism.

Is an alternative available?: Partially. Other manufacturers currently sell approved vena cava filters without a claim of recoverability, and there are also other medical and surgical options for some of these patients. However, there is only one other vena cava filter on the market with a claim of recoverability; this device has a similarly short marketing history to that of Recovery, no published clinical data, and an animal study that suggests incorporation of the struts into the caval wall after several weeks. Thus, the Recovery VC Filter may have unique advantages for certain patients.

Must the problem be corrected surgically?: Migration of vena cava filters to the heart is rarely managed conservatively, and treatment almost always requires either a percutaneous or open surgical correction.

Is the problem expected and within an acceptable statistical range?: Migration of vena cava filters, both within the vena cava and up to and into the heart are recognized complications of these devices. Acceptable statistical ranges cannot be reliably computed from available data, especially since many migrations without serious sequelae are not reported. Death associated with vena cava filter use, while a cruder measure, is probably subject to less under-reporting. Consideration of various estimates using this outcome measure do not demonstrate that these types of events are occurring with excess frequency with the Bard Recovery® Nitinol Vena Cava Filter. Such estimates are difficult to make reliably given the multiple data deficiencies noted above, and continued monitoring of event rates is warranted as further experience with the device is gained.

Can the problem be field corrected? In most of the serious or fatal complications involving vena cava filters (migration, caval perforation, caval occlusion and filter failure

with PE and / or acute respiratory failure) the device appears to be functioning normally up to the time of failure. Migration and filter failure generally occur when an otherwise normal filter is overwhelmed by aggregated large thrombus burdens. There is no device problem to be field corrected in this instance, just a recognized complication of vena cava filters.

Is it obvious to the user?: Migration of vena cava filters can be asymptomatic, but when they migrate to the heart this is clinically evident.

Can the product continue to be used with proper warnings?: Yes, the product can continue to be used with current warnings, which indicate the possibility of filter migration.

Is the device used only by specially trained health care professionals?: Yes, the device is only used by interventional radiologists and occasionally by other equally skilled interventionalists.

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EXHIBIT S

From: Ciavarella, David [/O=BARD/OU=MHL AG/CN=RECIPIENTS/CN=DCIAVARELLA]
Date: 12/27/2005 2:33:22 PM
To: Barry, Brian [Brian.Barry@crbard.com], Ganser, Christopher [Christopher.Ganser@crbard.com]
Subject: FW: G2 Caudal Migrations

My comments to Cindi and Gin.

_____

From: Ciavarella, David
Sent: Friday, December 23, 2005 2:32 PM
To: Walcott, Cindi
Cc: Allen, Shari; Schulz, Gin
Subject: RE: G2 Caudal Migrations

Thank you Cindi.

I think we should discuss these further so I can get a better understanding of each one. But first, it would help if I had a little more information.

From what you've sent me, it seems to me that the biggest (worst case) consequence of these migrations is that they are accompanied in a majority of cases by tilting. This raises the concern of lack of efficacy, that is, are the filters now in place to perform clot interruption? I would guess not in several of these cases at least.

I would like to look more generally at the G2 complaints. I have seen problems with caudal migration, tilting, perforation, mis-deployment and maybe one or two additional things. Can you tell me the total number of complaints (not damaged packages and the like) and total number of units distributed?

How many MDRs have we had for G2?

The G2 is a permanent filter; we also have one (the SNF) that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2? Can you also send me the total complaints rate and MDR complaint rate for SNF?

I'll be in the office next Tues and Wed; maybe we can talk one of those days.

David

_____

From: Walcott, Cindi
Sent: Tue 12/20/2005 6:14 PM
To: Ciavarella, David
Cc: Allen, Shari; Schulz, Gin
Subject: G2 Caudal Migrations

David,

During a conference call with the design team of the G2 filter and Chris Ganser today, the caudal migrations of the G2 were briefly discussed.

Chris asked if I had submitted any MDRs on these events yet and I answered yes. Chris asked me to review the events with you to determine what events have the potential for serious injury and establish a baseline for the future. Presently, based on the description of the events and the history of a filter being removed, I have coded them all as reportable. Please note that I cut the descriptions straight out of what was entered into Trackwise. I can see that some of the descriptions are a bit rough.

Please see the attachment, which has a description of the events to date.

1. Record 63855- I submitted that one as an MDR because there was also a report of perforation with this patient. Perforations have caused serious injuries with previous filters. We have always reported perforations of the Recovery Filter and the Simon Nitinol filters. The doctor also removed the filter due to the perforation and migration.
2. Record 65220- I submitted this one as an MDR, as the filter migrated into the renal veins and caused the patient flank pain.
3. Record 65851- I reported this one as it migrated 3cm and is currently at the iliac confluence.

Thanks for your assistance,

Cindi

EXHIBIT T
(Filed Under Seal)

EXHIBIT U

From: Rauch, David [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=DRAUCH]
Date: 2/27/2004 5:21:55 PM
To: Hudnall, Janet [Janet.Hudnall@crbard.com]
Subject: RE: Case for Caval Centering
Attachments: Rauch, David.vcf

Janet,
Thank-you for your valuable feedback. You are right; now that we have more experience with Recovery the positioning of tilt-resistance should probably be down played.
I will work on implementing your suggestions as well as those of the trainers and let you see the revised copy when it is done.

Dave Rauch
Bard Peripheral Vascular

-----Original Message-----
From: Hudnall, Janet
Sent: Thursday, February 26, 2004 2:01 PM
To: Rauch, David
Subject: Case for Caval Centering

Dave,

I wanted to comment on the training piece that you created. First of all, I'd like to applaud you for having pulled together a lot of good information.

Having said that, however, I must strongly caution against emphasizing Recovery's ability to center in the cava to the point where it is the focus of the product's positioning. We knew very little about the long-term clinical performance of this device when we launched it. After a year of commercialization, there are still many questions that need to be answered. One thing that we do know, however, is that Recovery does not always stay centered in the cava. In fact, physicians will often find that it is tilted quite a bit when they go to retrieve it even though it seemed perfectly centered upon deployment. So it seems to me that selling the device solely on this feature could set the sales rep up for some uncomfortable situations in the long run.

My opinion is that your document would be, in general, okay if it were positioned differently so that centering is not the focal point of its features and benefits. Also, I think that for a piece like this, it is critical to carefully reference the entire body of the text so that the reader can differentiate between what is documented in the literature and what is anecdotal/opinion.

Regards,
Janet

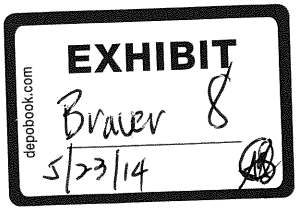


EXHIBIT V

Health Hazard Evaluation

DATE: December 17, 2004

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Recovery® Filter -- Consultant's report

Summary: Seventy-six reports of potentially serious hazards have been reported; 32 of these were judged to be serious, and 10 reports were associated with patient death. Total Recovery filter sales during this reporting period (through December 13, 2004) are 20,827 units. Reporting rates of death and other potentially serious complications for the Recovery filter remain below those reported in the literature. However, literature data are not directly comparable to these reporting rates. An analysis of reporting rates of serious adverse events for all inferior vena cava filters, as determined by analysis of the MAUDE and IMS databases by a consultant, revealed that reporting rates for Recovery are significantly higher than other filters. However, these databases are subject to known, significant biases that make calculation or comparison of incidence rates among products unreliable and inadvisable (according to experts and the FDA). Nevertheless, the number of reported complaints, and the size of the differences between Recovery and other filters, warrant further investigation.

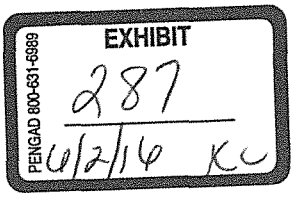
Conclusion: The Frequency category for serious injury (Critical Severity rating) is Occasional (32/20,827, or 0.153%). The Frequency category for non-serious injury (Marginal Severity rating) is Occasional (44/20,827, or 0.21%).

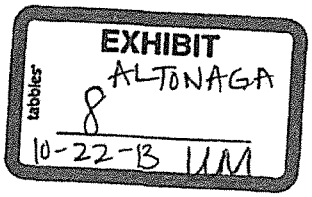
Description of the Problem: Based on awareness of reports of patient death associated with migration of the Recovery inferior vena cava (IVC) filter, Bard requested an independent study of the risks and benefits of the Recovery filter, with an emphasis on its use in bariatric surgery and trauma patients. A consultant was retained for this purpose. The consultant's assignment had three components: 1) Perform a literature review of the risks and benefits of IVC filters, with an emphasis on bariatric surgery and trauma patients; 2) Review internal complaint files for the Recovery filter, and compare its reported adverse events rates to those of competitors' IVC filter by use of the MAUDE and IMS (sales) databases or other means; & 3) develop options for clinical studies that might provide information required to assess the risks and benefits of use of the Recovery filter.

The consultant made the following points:

1) The existing literature is of poor quality, with insufficient randomized, controlled trials (RCT) to definitively establish the effectiveness of IVC filters. However, widespread consensus exists in the medical community, obtained via clinical studies of lower credibility than the RCT (such as case reports, case series and prospective non-randomized studies of small size) and expert opinion, that IVC filters lower the likelihood of death from pulmonary embolus in patient groups thought to be at highest risk of this manifestation of venous thromboembolic disease. These high risk groups include patients who have already had a pulmonary embolus or in whom standard anticoagulation therapy cannot be given. However, the existing literature contains comparatively little information on a new generation of IVC filters, especially those with a removability feature (Recovery, Cook Tulip™ and Cordis OptEase™).

   Proper product comparisons can be only be drawn from clinical studies where patient populations are carefully defined, comparisons are made under controlled circumstances from equivalent pa-





tient groups, and adverse events are prospectively defined and sought for in an effective manner. Such studies do not exist for the Recovery filter or its competitors. Therefore, the consultant judged that the literature is an inadequate source of reliable information upon which to make a risk/benefit assessment for the Recovery filter, either alone or in comparison to other IVC filters.

2) The consultant's analysis of the reports to Bard of adverse events associated with Recovery, along with competitors' information available via the MAUDE and IMS databases, showed the following:

   a. Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters. These differences were all statistically significant. Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters. The TrapEase filter was found to have a statistically significant increased reporting rate for IVC thrombosis when compared to reporting rates for other filters.

   b. These reported adverse event rates were analyzed in conjunction with a bench test performed at BPV. This test measured "migration resistance" in a simulated IVC. Recovery filter had the lowest mean migration resistance (50 mm Hg), just below that of the removable Tulip filter (55 mm Hg). Linear regression analysis showed a significant inverse correlation (R^2 values of 0.40 to 0.65) of reported migration rates to the migration resistance values in the bench test.

   c. An analysis of the quality and validity of this analytical approach (use of MAUDE and IMS databases to generate comparative event rates), however, was performed as well. Many references were found that discussed the inadvisability of using MAUDE data for this purpose. Reported event data are seriously flawed, due to underreporting, various acknowledged forms of bias (such as the known propensity for more reports of adverse events in newer products), and confounding effects (such as lack of comparability in patient groups). The FDA has stated that such an approach is "...problematic, if not completely biased" [1] and "Accumulated reports cannot be used to calculate incidence or to estimate drug risk. Comparisons between drugs cannot be made from these data.". [2] Similar biases were discussed for use of the IMS sales data, in particular, the known lag period that exists between data collection and data publication, leading to large biases in data for products that are new or where indications are in evolution. Thus, actual incidence rates cannot be determined by this approach; these data are better interpreted as providing a signal for further investigation.

   d. A risk/benefit assessment has not been done, because the potential unique benefits of the Recovery filter (e.g., in certain patient groups) have not been evaluated as part of the consultant's report.

3) Little formal analysis has been completed with respect to potential clinical trials to obtain more definitive risk/benefit information. A randomized, controlled trial is the gold standard for determining risks and benefits; however, such a study is likely to require many subjects and therefore be difficult or impossible to execute. The consultant stated that a survey of physicians regarding their use of IVC filters and/or an analysis of data from a large payor or provider organization might be alternative approaches that might provide useful information in a shorter timeframe.

In addition to the consultant's report, a case-by-case analysis of all reported Recovery complaints as of December 13, 2004 related to filter migration, filter fracture, IVC thrombosis, IVC perforation and recurrent pulmonary embolus was performed.

The Actual Occurrence of Injuries: Serious injury is defined here as reported death, or necessity for a surgical intervention to prevent death or serious injury. Reported recurrent pulmonary embolus or IVC thrombosis despite the presence of the filter were also classified as serious injury. In addition, migration of a filter or filter fragments to the heart or lung, or the presence of a filter fragment outside the vasculature, were classified as serious injury, since there is a possibility that serious injury could develop in the future.

With these criteria, there were a total of 32 reported serious injuries, a reporting rate of 0.153%. Details of these reports are given below.

Human Exposure to the Problem: About 20,827 Recovery filters have been distributed as of December 13, 2004.

General Consequences: The consequences of reported adverse events associated with the Recovery IVC filter depend upon the kind of event. Filter migration to the heart, especially when the filter is encased in thrombus, has been associated with sudden death. In some cases, filter migration is associated with trapping of clot before it reaches the heart, and it continues to perform its primary function despite the migration. Filter fracture may be asymptomatic, but has been associated with fragment embolization to the heart causing syncope and/or arrhythmias. IVC perforation is also generally asymptomatic, but it can lead to serious bleeding and, if occurring in conjunction with filter limb fracture, may be associated with fragment migration outside the IVC to nearby organs.

Population Exposed to the Risk: All patients in whom a Recovery filter is placed are potentially at risk for filter-associated adverse events.

Mitigating/Predisposing Factors in the Population at Risk: Unknown.

Nature & Seriousness of the Risk: The nature of the injury is generally related to the cardiovascular system, such as pulmonary embolus, myocardial or pericardial puncture or damage, or bleeding. There was one case of renal vein thrombosis requiring dialysis, listed as a serious event because the filter migrated above the renal veins, thus potentially allowing clot in the lower IVC to propagate to the renal veins. However, it is also possible that renal vein thrombosis developed because of the underlying disease and was unrelated to the filter migration. There was one case of reported IVC thrombosis in a patient in whom recurrent pulmonary embolus was also reported. No further information about this case is available at this time.

The seriousness of the risk ranged from reports of patient death to no effects. There were 10 reports of death. One death was reported in association with recurrent PE, while the other 9 were associated with filter migration. Six (6) of these migration-associated deaths were migrations to the heart of a thrombus-encased filter. In a seventh case, only a small amount of clot was attached to the filter, but large clots were present in the pulmonary arteries. In one case, it was not known whether the filter contained clot, and in the remaining 2 cases, physicians judged the deaths to be unrelated to the filter. In the first of these 2 cases, the filter, without adherent clot, flowed out of the ventricle at autopsy. A chest X-ray taken during CPR and just prior to death did not reveal the filter in the heart, and migration to the heart may have occurred due to CPR or post mortem. In the second case, a CT scan performed minutes prior to death revealed migration to the upper IVC. In this case, an autopsy was not performed, and the physician stated that death was not related to the filter.

Likelihood of Occurrence of the Problem: The number, severity classification and type of complication (hazard) reported for the Recovery filter are summarized in Table I.

Table I. Reporting Rates for Adverse Events Associated with the Recovery Filter

Hazard type	Total	Reporting Rate	Serious Injury(as above)	Reporting Rate
Death	10(8*)	0.048%(0.038%*)	10(8*)	0.048% (0.038%*)
Migration	25	0.12%	16 (14*)	0.077% (0.067%*)
Fractures	33	0.158%	12	0.058%
Perforation	15	0.072%	1	0.005%
P. embolus	3	0.014%	3	0.014%
[IVC Thrombosis	1**	0.005%	1	0.005%]
Total	76**	0.365%	32 (30)	0.153% (0.149%)

* Number and rates if the 2 migration-associated deaths that were judged not related to the filter are excluded.
** Recurrent pulmonary embolism was also reported in this case; therefore, the total number of patients/reports is listed as 76 and not 77.

A summary of reported rates for these filter-related complications in the literature is provided in Table II..[3] These rates refer to the use of permanent, non-removable filters.

Table II. Reported Rates of IVC Filter Complications Provided by Literature Review.
Threshold levels are quality improvement guidelines published by the Society of Interventional Radiologists.
Reference: Grassi CJ, Swan TL, Cardella JF et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.

Hazard type	Reported rates		Threshold (for review)
Death	0.12%		< 1%
Filter Embolization*	2-5%	2%	
Fractures	2-10%		Not listed
Perforation	0-41%		Not listed
P. embolus	0.5-0.6%		5%
IVC Occlusion**	2-30		10%

* This is equivalent to Migration in the Table above listing Recovery reporting rates
** This is equivalent to IVC Thrombosis in the Table above

Likelihood of Harm if the Problem Occurs: See above for the reporting rates of serious injury, defined as described in The Actual Occurrence of Injuries.

Is the Product Essential to Health: Yes, in selected patient groups. As mentioned above, a general consensus exists for the utility of IVC filters in high risk patient groups despite the lack of definitive RCTs.

Is there an Alternative Available: Yes. Alternative permanent and removable IVC filters exist. However, the Recovery filter is unique in the length of the implant period. The Recovery implant period is not limited in the Recovery instructions for use (IFU), and can be utilized as a permanent filter. The clinical experience for the other removable filters, as discussed in the product IFUs, reports short implant periods (mean implant period about 2-3 weeks) before filter removal must be undertaken.

Must the Problem Device be Removed or Corrected Surgically: Yes, in some cases.

Is the Problem Expected & Within an Acceptable Statistical Range: From the analysis of the MAUDE and IMS databases, Recovery reporting rates are significantly higher than those of other filters. In conjunction with these data, there appears to be a significant correlation, although R^2 values are only in the 0.5 range, of the migration reporting rates with the simulated migration resistance bench test. However, the flaws in the data collection methodologies makes calculation and comparison of actual incidence rates impossible from these data, and no definitive conclusions as to relative performance can be made. Adverse events rates reported in the literature are well above these reporting rates. But, as discussed above, direct comparisons of reporting rates to literature-derived rates are not possible because mostly permanent filters have been studied and the data have been collected using markedly different detection methods and patient populations. However, further investigation of these reported adverse events is warranted because of the size of the differences in the reporting rates and the correlation with the bench test of migration resistance.

Can the Problem be Corrected in the Field: No.

Is the Problem or Health Hazard Obvious to the User: No.

Can the Product Continue to be Used with Proper Warnings: One could consider providing summary information concerning the analysis of reporting rates to physicians in the context of the limitations of the data. Further work into the collection of survey data from surgeons or payors might be explored.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

References:

[1]. Goldman SA. Limitations and strengths of spontaneous reports data. Clin Ther 1998; 20 Suppl C: C40-44.

[2]. Jones JK. Spontaneous reports cannot serve as a basis for comparison of two drugs. Am J Cardiol 2003;92:1141-1142.

[3]. Grassi CJ, Swan TL, Cardella JF, et al: Quality improvement guidelines for percutaneous permanent inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2003;14:S271-S275.

EXHIBIT W

G2® Filter System

Timeless Performance®

G2 Filter System

Femoral Vein Approach

ENGLISH

Instructions for Use

For use in the Vena Cava

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information

The G2 Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the G2 Filter provide filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer catheter with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned 1 cm below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the G2 Filter to be deployed with the filter tip centered and minimizes the potential for legs crossing.

The G2 Filter is designed to act as a permanent filter. When clinically indicated, the G2 Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The G2 Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (Reference Optional Procedure for Filter Removal for specific removal instructions.)

MRI Safety:

Non-clinical testing has demonstrated that the G2 Filter is MR Conditional. It can be scanned safely under the following conditions:

1. Static Magnetic field of 1.5-Tesla or less;
2. Spatial gradient field of 450 Gauss/cm or less
3. Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the G2 Filter produced a temperature rise of less than or equal to 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5-Tesla, General Electric Healthcare MR scanner. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the G2 Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

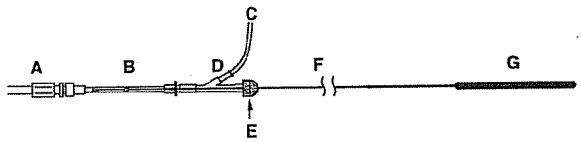
B. Device Description

The G2 Filter System - Femoral consists of the filter and delivery system. The G2 Filter consists of twelve, shape-memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The G2 Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

The G2 Filter System - Femoral is illustrated in Figure A. The delivery system consists of a 7 French I.D. introducer catheter and dilator, the G2 Filter, a storage tube with saline infusion port, and a pusher system. The G2 Filter is packaged pre-loaded within the delivery storage tube

C. Indications for Use

Figure A. G2® Filter System - Femoral



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read Instructions carefully before using the G2 Filter

The G2 Filter System - Femoral is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- G2 Filter may be removed according to the instructions supplied below under Section labeled: Optional Procedure for Filter Removal.

D. Contraindications for Use

CAUTION: If the IVC diameter exceeds 28 mm, the filter must not be inserted into the IVC.

The G2® Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with an IVC diameter larger than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

G2® Filter Implantation

1. The G2 Filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the IVC, as the G2 Filter cannot be safely reloaded into the storage tube.
2. Do not deploy the filter unless IVC has been properly measured. (Refer to Precaution # 4.)
3. Delivery of the G2 Filter through the introducer catheter is advance only. Retraction of the pusher wire during delivery could result in dislodgment of the filter, crossing of filter legs or arms, and could prevent the filter from further advancement within the introducer catheter.
4. The G2 Filter System - Femoral is designed for femoral approaches only. Never use the G2 Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper G2 Filter orientation within the IVC.
5. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it as migration of the clot and/or filter may occur. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer catheter.
6. Only use the *Recovery Cone*® Removal System to remove the G2 Filter. Never re-deploy a removed filter.
7. Never advance the guidewire or introducer catheter/dilator or deploy the filter without fluoroscopic guidance.
8. Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
9. Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
10. Persons with allergic reactions to nickel may suffer an allergic response to this implant.
11. After use, the G2 Filter System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

See Potential Complications section for further information regarding other known filter complications.

G2® Filter Removal

1. Do not attempt to remove the G2 Filter if significant amounts of thrombus are trapped within the filter or if the filter tip is embedded within the vena cava wall.
   NOTE: It is possible that complications such as those described in the "Warnings, Precautions, and Potential Complications" section of this Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.
2. Use only the Bard *Recovery Cone* Removal System (packaged separately) to retrieve the G2 Filter. Use of other removal devices has resulted in recurrent pulmonary embolism.
3. Never re-deploy a removed filter.

F. Precautions

G2® Filter Implantation

1. This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques.
2. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.[1]
3. Anatomical variances may complicate filter insertion and deployment. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
4. Position the filter tip 1 cm below the lowest renal vein. Venacavography must always be performed to confirm proper implant site. Radiographs without contrast, which do not clearly show the wall of the IVC, may be misleading
5. When measuring caval dimensions, consider an angiographic catheter or IntraVascular Ultrasound (IVUS) if there is any question about caval morphology.
6. If misplacement or sub-optimal placement of the filter occurs, consider immediate retrieval. Retrieve the G2 Filter using the *Recovery Cone* Removal System only. Refer to the Optional Procedure for Filter Removal section for details.
7. Spinal deformations: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.
8. In patients with continued risk of chronic, recurrent pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
9. If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and use the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
10. The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
11. The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage of the hub.
12. It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become covered by clot. This will interfere with filter deployment.
13. Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter. Do not twist the pusher wire handle at anytime during this procedure.

G2® Filter Removal

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone* Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. Spinal deformations: It is important to exercise care when contemplating removing the G2 Filter with the *Recovery Cone* Removal System in patients with significant kyphoscoliotic spinal deformations because the IVC may follow the general course of such anatomic deformations. This may require advanced interventional techniques to remove the filter
3. Remove the G2 Filter using the *Recovery Cone* Removal System Only. (Reference Optional Procedure for Filter Removal for specific removal instructions).
4. The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

G. Potential Complications

Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to, the following:

- Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
- Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
- Perforation or other acute or chronic damage of the IVC wall.
- Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels.
- Caval thrombosis/occlusion.
- Extravasation of contrast material at time of venacavogram.
- Air embolism.
- Hematoma or nerve injury at the puncture site or subsequent retrieval site.
- Hemorrhage.
- Restriction of blood flow.
- Occlusion of small vessels.
- Distal embolization.
- Infection.
- Intimal tear.
- Stenosis at implant site.

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

H. Equipment Required

The following equipment is required for use.

- One G2 Filter and Delivery System that contains:
  - -One 48 cm, 7 French I.D. introducer catheter and dilator set
  - -One storage tube with pre-loaded G2 Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

If the physician chooses to percutaneously remove the G2 Filter, the ***Recovery Cone***® Removal System is available from C. R. Bard, Inc.

I. Directions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

Precaution: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.

6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

Precaution: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.

7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the introducer catheter a constant saline drip infusion to maintain introducer catheter patency.

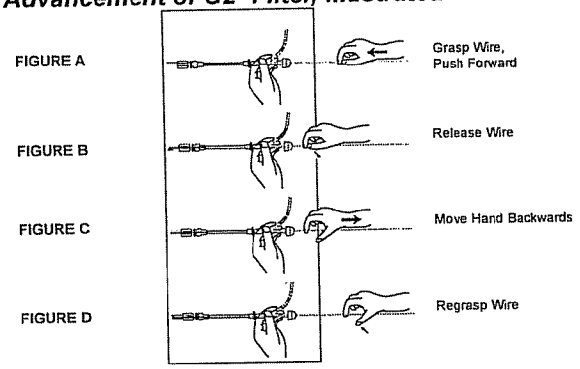
Precaution: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.

8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion, the introducer catheter tip should be 1 cm below the lowest renal vein.
10. Remove the filter and delivery system from Kit B and flush with saline.

Precaution: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

11. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
12. Advance the filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the filter with each forward motion of the pusher wire (Figures A-D). Do not pull back on the pusher wire, only advance the pusher wire forward. For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.

Advancement of G2® Filter, Illustrated

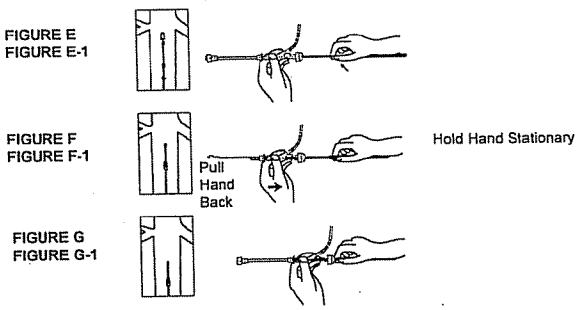


13. Continue forward movement of the pusher wire until the filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

14. Deliver and release filter as described below.
    Figure E: Firmly hold the pusher wire handle. Keep this hand stationary throughout the entire filter release/deployment process.
    Figure E-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

G2® Filter Release, Illustrated



Precaution: Do not deliver the filter by pushing it beyond the end of the introducer catheter. To achieve proper placement, unsheath the stationary filter by withdrawing the introducer catheter as described below. Do not twist the pusher wire handle at anytime during this procedure.

Position the filter tip 1 cm below the lowest renal vein.

Figure F: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter. Ensure that there is no slack or bend in the system during the filter release/deployment process. The Y-adapter and storage tube assembly should be retracted in one smooth, continuous motion.

Figure F-1: Unsheathing of filter in IVC.

Figure G: The position of the hands at the completion of the unsheathing process.

Figure G-1: The filter deployed in the IVC.

15. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and introducer catheter assembly and pulling back on the pusher wire. Do not twist the pusher wire handle at anytime during this procedure.
16. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30mL of contrast medium at 15mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

CAUTION: Remove the G2 Filter using the *Recovery Cone* only.

Removal of G2® Filter

Equipment Required

The following equipment is required for use:

- One ***Recovery Cone*** Removal System that contains:
  - –One 75 cm, 10 French I.D. introducer catheter and dilator set
  - –One Y-adapter with ***Recovery Cone*** and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- 12 French dilator
- Saline
- Contrast medium
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc.

Clinical Experience

A clinical study involving 100 patients was conducted to assess the safety of removal of the G2 Filter. 61 patients underwent a filter retrieval procedure in which 58 had successful retrieval of their filter. Of the 42 patients that did not have their filter retrieved, 6 died of unrelated causes, 3 withdrew, 2 became lost to follow up and 31 were either not clinically indicated for filter retrieval or failed to meet retrieval eligibility criteria during the period in which the patient could be considered for filter retrieval per the protocol (within 6 months after filter placement.) The mean age of the 61 patients who underwent a retrieval procedure was 48 years with a range of 19.3-81.6. The indications for filter placement included DVT and/or PE with contraindication to anticoagulation, DVT and/or PE with complication or failure of anticoagulation, and prophylaxis.

The time to retrieval in the 58 patients with successful filter retrievals ranged from 5 to 300 days with a mean of 140 days and median of 144 days. Please see the histogram in Figure H depicting the time to retrieval.

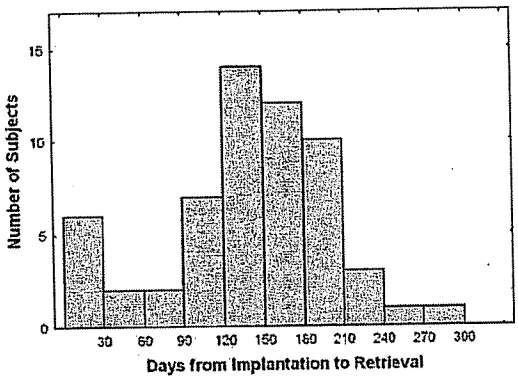


Figure H: Distribution of Filter Indwell Time in Retrieved Subjects

Of the 61 attempted filter retrievals, 3 technical failures for retrieval resulted from inability to engage the filter apex with the ***Recovery Cone®*** Removal System due to filter tilt leading to embedding of the filter apex into the vena caval wall. One of the 58 successful filter retrievals involved a filter that was retrieved in spite of tilt and associated embedding of filter apex into caval wall.

There was one symptomatic complication in the study. A patient reported low back pain after a successful filter placement. On pre-retrieval imaging, two (2) of the filter arms were found to be penetrating the caval wall. The filter was successfully retrieved and the pain resolved.

Asymptomatic complications included caudal migration (n=10), fracture (n=1), PE (n=2), filter tilt (n=15), penetration (n=17), caval occlusion (n=1), non-occlusive caval thrombosis (n=1), and caval stenosis at implant site post successful retrieval (n=1).

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference, or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the ***Recovery Cone*** Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the **G2®** Filter for removal.
6. Remove the venipuncture needle over the guidewire.
7. Pre-dilate the accessed vessel with a 12 French dilator.
8. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.

9. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
10. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. If there is significant thrombus within the filter, do not remove the **G2** Filter.

***Recovery Cone* Removal System Insertion and Delivery**

11. Remove the ***Recovery Cone*** Removal System and pusher system from Kit B.
12. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
13. Slowly withdraw the cone into the Y-adapter to collapse the cone and flush with saline.

PRECAUTION: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be properly delivered through the catheter.

14. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
15. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
16. Continue forward movement of the pusher shaft until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheath to open the cone by stabilizing the pusher shaft and retracting the introducer catheter.

Capture of G2® Filter

G2® Filter Removal, Illustrated

17. The capture of the **G2** Filter is illustrated in **Figures A-E**:

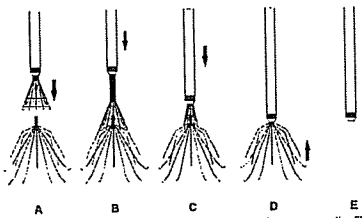


Figure A: After the cone has been opened superior to the filter, advance the cone over the filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the filter tip.

Figure B: Close the cone over the filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

Figure C: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

Figure D: With the cone collapsed over the filter, remove the filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

Figure E: The filter has been retracted into the catheter

18. Examine the filter to assure that the complete filter has been removed.

Follow-up Venacavogram

19. A follow-up venacavogram may be performed prior to withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
20. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the **G2** Filter, guidewire-assisted techniques may be used.

Use of a Guidewire

If it is difficult to align the cone with the **G2** Filter tip, one may use a guidewire to facilitate advancement of cone over the filter tip. Withdraw the introducer catheter and cone shaft away from the filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the filter near the filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the filter tip, advance the cone over the guidewire to the filter tip.

Advance the introducer catheter to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft. Continue removing the Filter as described in step 17.

J. How Supplied

Each **G2** Filter is supplied preloaded in a storage tube. Each **G2** Filter is sterile and nonpyrogenic unless the package is damaged or opened, and is ready for single use only. The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, do not attempt to re-sterilize or reload it.

Warning: After use, the G2 Filter Delivery System and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

The **G2** Filter should be stored in a cool (room temperature), dry place

K. Warranty

Bard Peripheral Vascular warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard Peripheral Vascular's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL BARD PERIPHERAL VASCULAR BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact Bard Peripheral Vascular to see if additional product information is available

References:

1. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. Grassi, Swan, Cardella, et al.: J Vasc Interv Radiol 2003; 14:S271-S275.
2. Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter. Asch, M.. Radiology 2002, 225(3), 835-844.
3. Retrievability of the Recovery Vena Cava Filter after Dwell Times Longer than 180 Days. Binkert, C., et al.: J Vasc Interv Radiol 2006, 17(2), 299-302.
4. Experience with the Recovery Filter as a Retrievable Inferior Vena Cava Filter. Grande, J., et al.: J Vasc Interv Radiol 2005, 16(9), 1189-1193.
5. Difficult Retrieval of a Recovery IVC Filter. Hagspiel, K., et al.: J Vasc Interv Radiol 2004, 15(6), 645-647.
6. Removal of Vena Cava Filter at 224 Days. Lipman, J.: Southern Medical Journal 2005, 98(5), 556-558.
7. Retrieval of the Bard Recovery Filter from a Superior Vena Cava. Rajan, D., et al.: J Vasc Interv Radiol 2004, 15(10), 1169-1171.
8. Retrievable Inferior Vena Cava Filters. Initial Clinical Results. Rosenthal, D., et al.: Annals of Vascular Surgery 2006, 20(1), 157-165.

G2® Filter System

Femoral

Femoral Introducer Catheter

Use By

Lot Number

Catalog Number

Attention, See Instructions for Use

Sterilized By Using Ethylene Oxide

Non-pyrogenic

Single Use.

Do Not Resterilize.

Do Not Use If Package Is Damaged Or Opened.

MR Conditional

Contents: Kit A: One (1) 7 Fr. Introducer Catheter 48cm Long with Dilator
Kit B: One (1) G2 Filter Femoral Delivery System

Protect From Heat

Keep Dry

Recommended Guidewire

Manufactured By:

Bard, G2, Recovery Cone and Timeless Performance are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Variously protected by one or more of the following U.S. Patents: 6,007,558 and 6,258,026. Other U.S. and Foreign Patents Pending.

Manufactured By:
Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, AZ 85281
USA

TEL: 1-480-894-9515
1-800-321-4254
FAX: 1-480-956-7062
1-800-440-5376
www.bardpv.com

BARD PERIPHERAL VASCULAR

PK5250500 Rev. 0 01/08

EXHIBIT X
(Filed Under Seal)

EXHIBIT Y

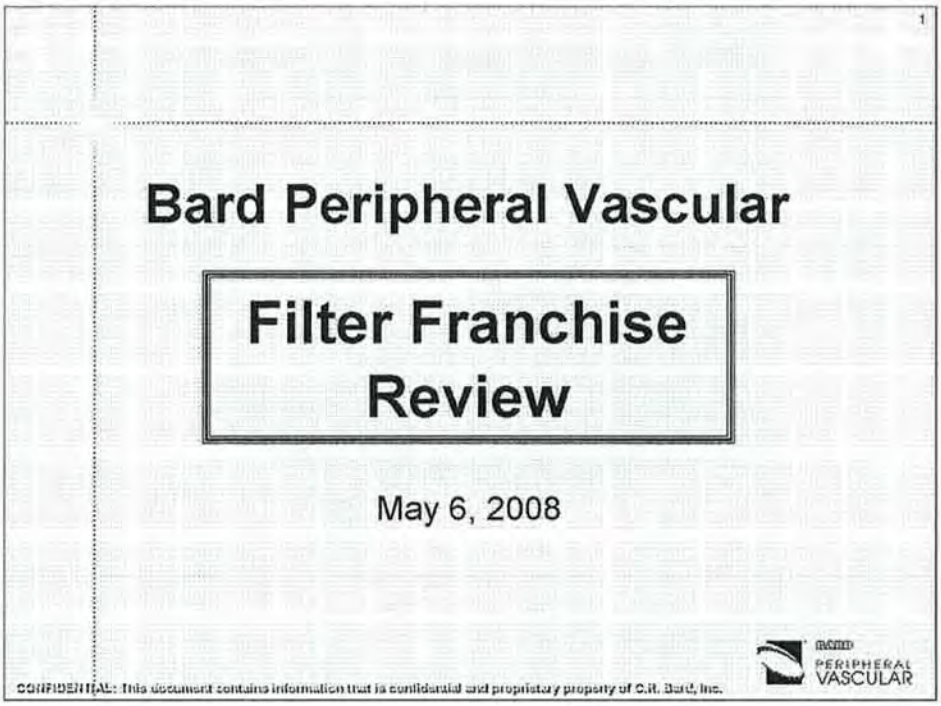
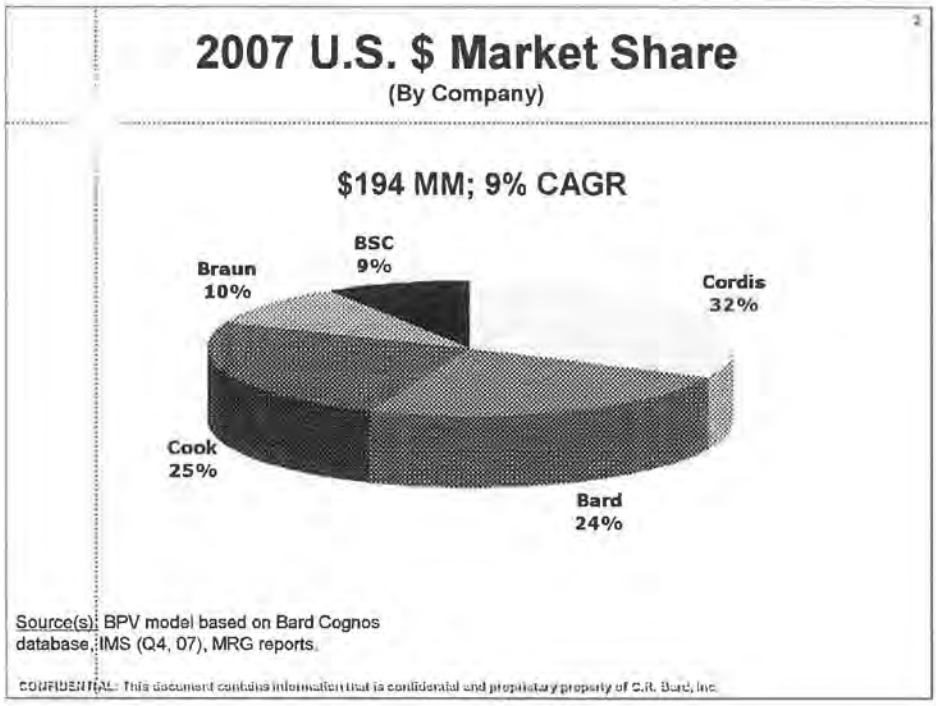


EXHIBIT NO. 14
TESMER
6/12/13


2007 U.S. $ Market Share
(By Company)
$194 MM; 9% CAGR
BSC
9%
Braun
10%
Cordis
32%
Cook
25%
Bard
24%
Source(s): BPV model based on Bard Cognos database, IMS (Q4, 07), MRG reports.
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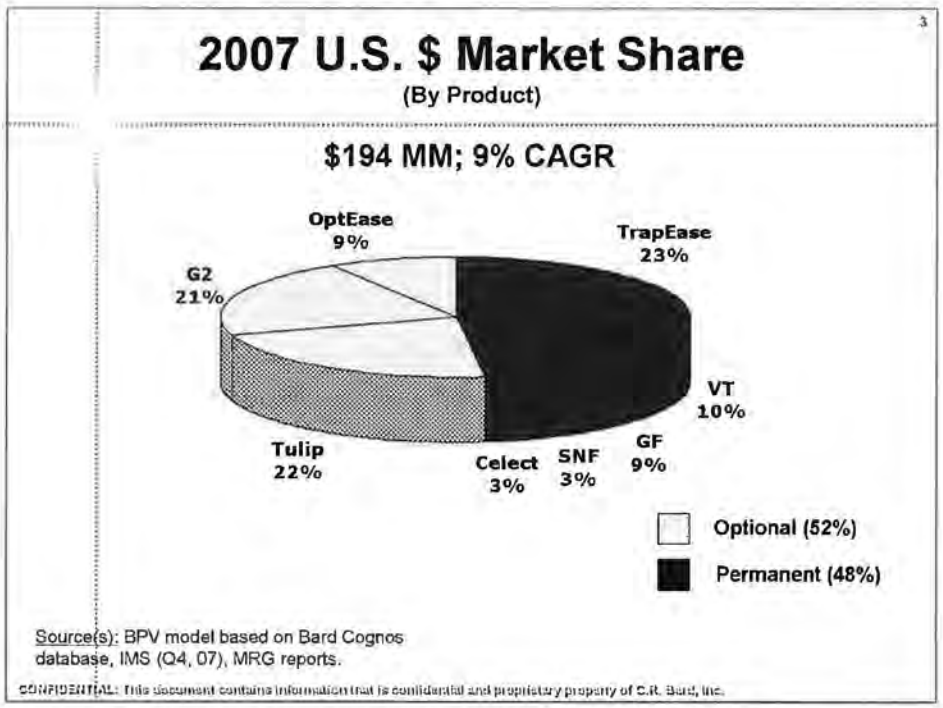

- Celect estimated to be about 3% of the Cook number
- Does not much news, seems to be more of a LMR. Not even showing up on our internal tracking info from HSI
- OptEase has been at 9% for a while. TrapEase users like idea of retrievable but the filter has not attained broader market acceptance, indwell time is probably one of the bigger reasons

•No permanent filters being developed, everything is being designed to be optional

•Field big source of info, Corporate, VP of Reimbursement Dave Parr, coded as foreign body retrieval 37203

•ASC = Ambulatory Service Center

•New entrants lack of good filter data, filters perceived as last resort, medical community not know answer, anticoag has its own problems


5
Key Market Trends (cont.)
• But the Optional Market Growth is being hampered:
– Recent clinical data focuses on complications associated with optional filters
– There is a perceived risk / benefit tradeoff for marginally indicated patients with the attitude there is no "benign" filter
– Insufficient implant referral base awareness of possible benefits of optional filters
– Lack of education opportunities to implant & retrieve
– Poor tracking in hospitals for follow up retrieval (tracking software value)
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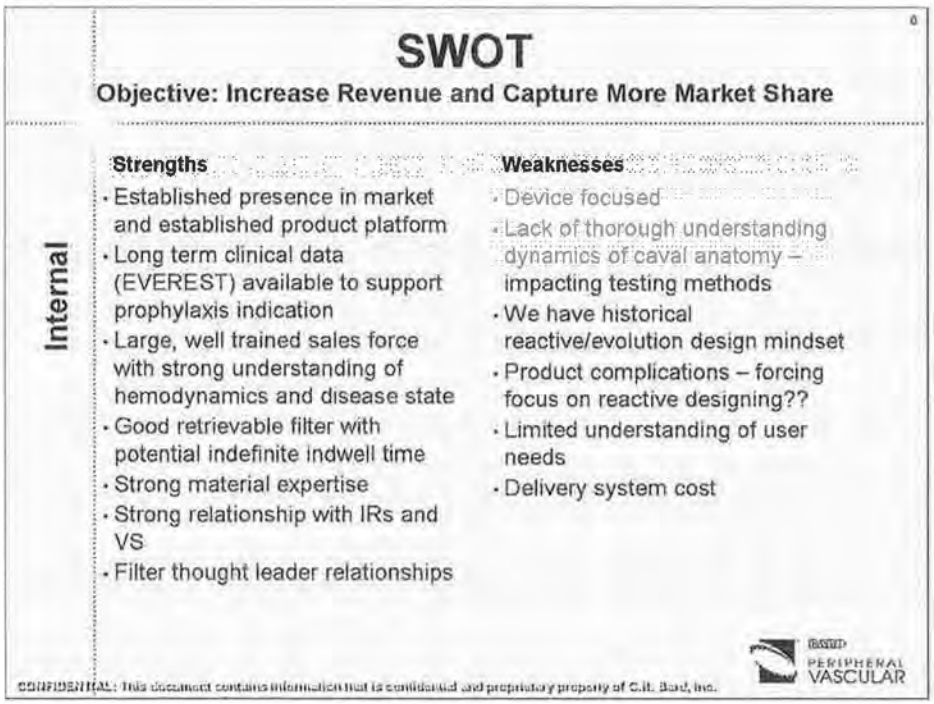
SWOT
Objective: Increase Revenue and Capture More Market Share
Internal
Strengths
• Established presence in market and established product platform
• Long term clinical data (EVEREST) available to support prophylaxis indication
• Large, well trained sales force with strong understanding of hemodynamics and disease state
• Good retrievable filter with potential indefinite indwell time
• Strong material expertise
• Strong relationship with IRs and VS
• Filter thought leader relationships
Weaknesses
• Device focused
• Lack of thorough understanding dynamics of caval anatomy – impacting testing methods
• We have historical reactive/evolution design mindset
• Product complications – forcing focus on reactive designing??
• Limited understanding of user needs
• Delivery system cost
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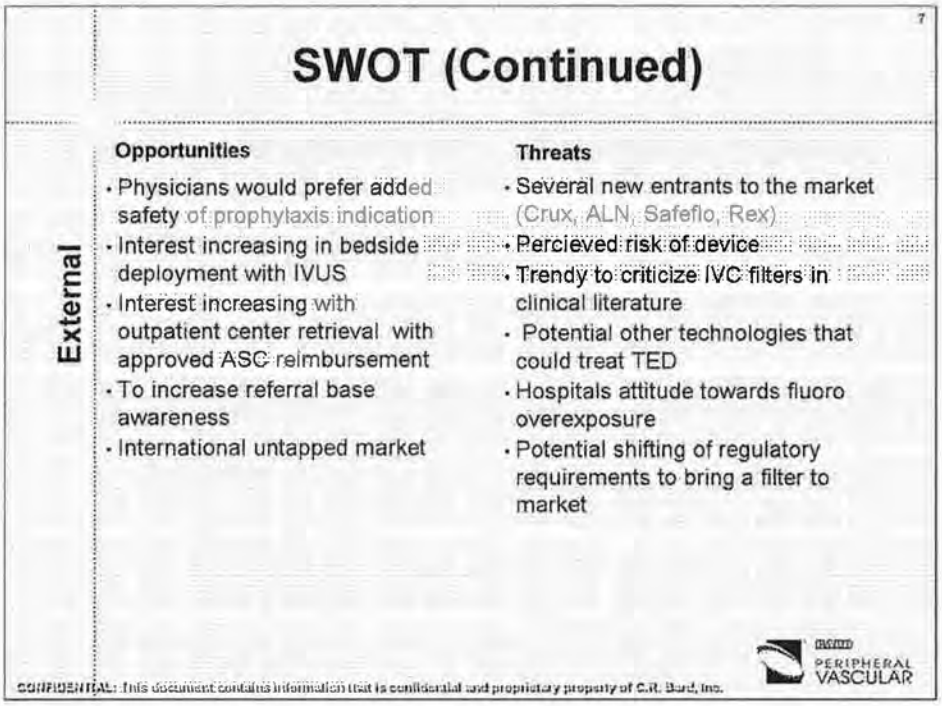
7
SWOT (Continued)
External
Opportunities
• Physicians would prefer added safety of prophylaxis indication
• Interest increasing in bedside deployment with IVUS
• Interest increasing with outpatient center retrieval with approved ASC reimbursement
• To increase referral base awareness
• International untapped market
Threats
• Several new entrants to the market (Crux, ALN, Safeflo, Rex)
• Percieved risk of device
• Trendy to criticize IVC filters in clinical literature
• Potential other technologies that could treat TED
• Hospitals attitude towards fluoro overexposure
• Potential shifting of regulatory requirements to bring a filter to market
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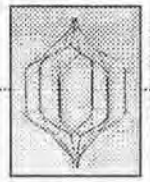
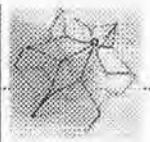
Cordis





- Market Leader
  - 37% Market Share ($); 36% (units)
- Product Offering
  - **TrapEase** (Permanent)
  - **OptEase** (Optional)

Strengths	Weaknesses
Ease of use Bi-directional filter Low Profile Low price Retrieval indication (Optease)	Inverted conical design Perceived caval thrombosis issues Lack of support from filter thought leaders Short window of retrievability

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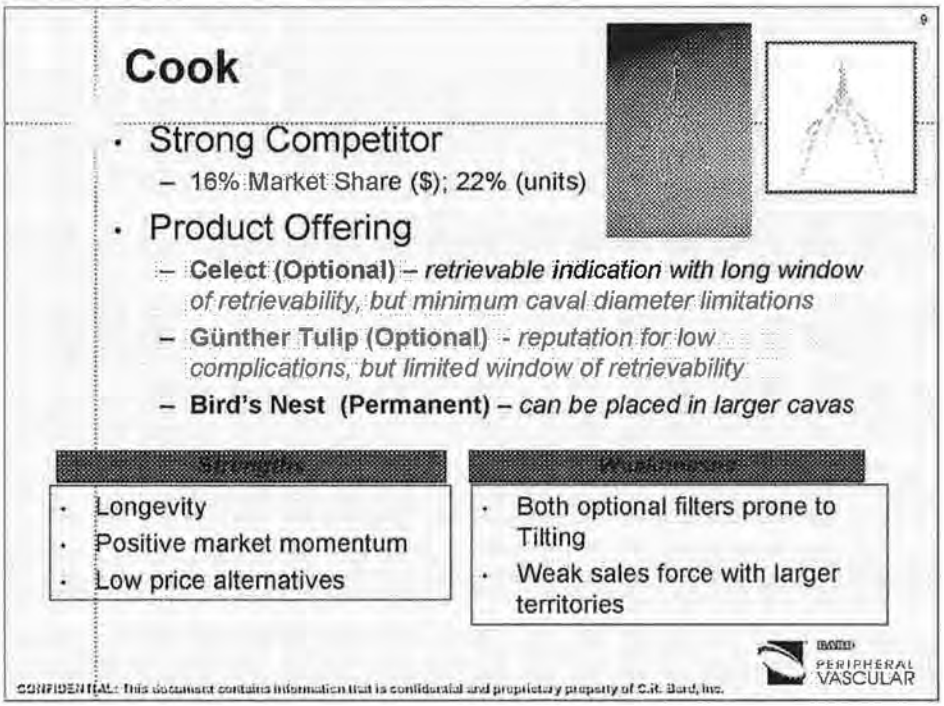
Cook
• Strong Competitor
– 16% Market Share ($); 22% (units)
• Product Offering
– Celect (Optional) – retrievable indication with long window of retrievability, but minimum caval diameter limitations
– Günther Tulip (Optional) - reputation for low complications, but limited window of retrievability
– Bird's Nest (Permanent) – can be placed in larger cavas
• Longevity
• Positive market momentum
• Low price alternatives
• Both optional filters prone to Tilting
• Weak sales force with larger territories
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10

Other Permanent (BBraun & Boston)

- BBraun
  - 13% Market Share ($); 13% (units)
  - **Vena Tech LP and LGM** (Permanent) – *bidirectional filters, easy to use with low prices and perceived low complication rates, but no dual level filtration and weak sales force*
- Boston Scientific
  - 9% Market Share ($); 10% (units)
  - **Greenfield SS and Ti** (Permanent) – *clinic history and strong sales force supporting ease of use and low price, but no dual level filtration and prone to tilt; larger profile as well with single femoral side delivery*

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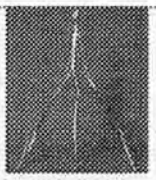
11

Other New Entrants

- Rex Medical (Option Filter)
  - Low profile and optional, but no real new technology advancements
- ALN (ALN Filter)
  - Optional filter marketed by distributor in U.S.; tilting risks
- Rafael Medical (SafeFlo Filter)
  - Optional filter
- BBraun (Convertible Filter)



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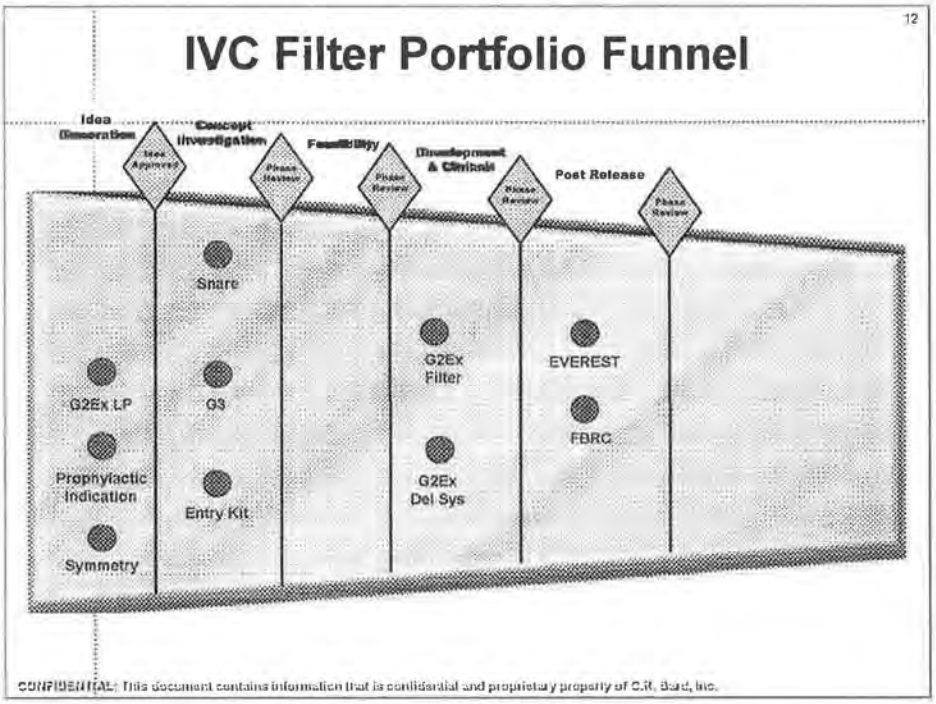
12
IVC Filter Portfolio Funnel
Idea Generation
Idea Approved
Concept Investigation
Phase Review
Feasibility
Phase Review
Development & Clinical
Phase Review
Post Release
Phase Review
Snare
G2Ex LP
G3
G2Ex Filter
EVEREST
FBRC
Prophylactic Indication
Entry Kit
G2Ex Del Sys
Symmetry
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13
U.S. Filter Sales History
Sales ($ Million)
50
45
40
35
30
25
20
15
10
5
0
$12.1
$16.1
$30.8
$31.9
$36.3
$45.9
$6.4
$39.3
$28.9
'02
'03
'04
'05
'06
'07
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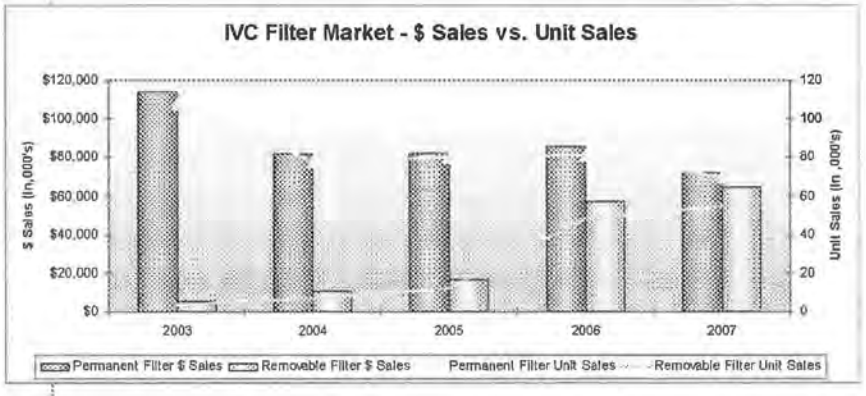
14

Permanent vs. Optional Sales History

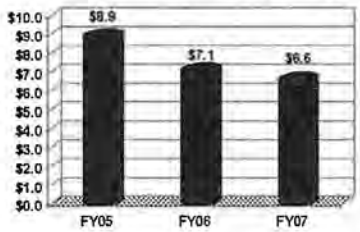


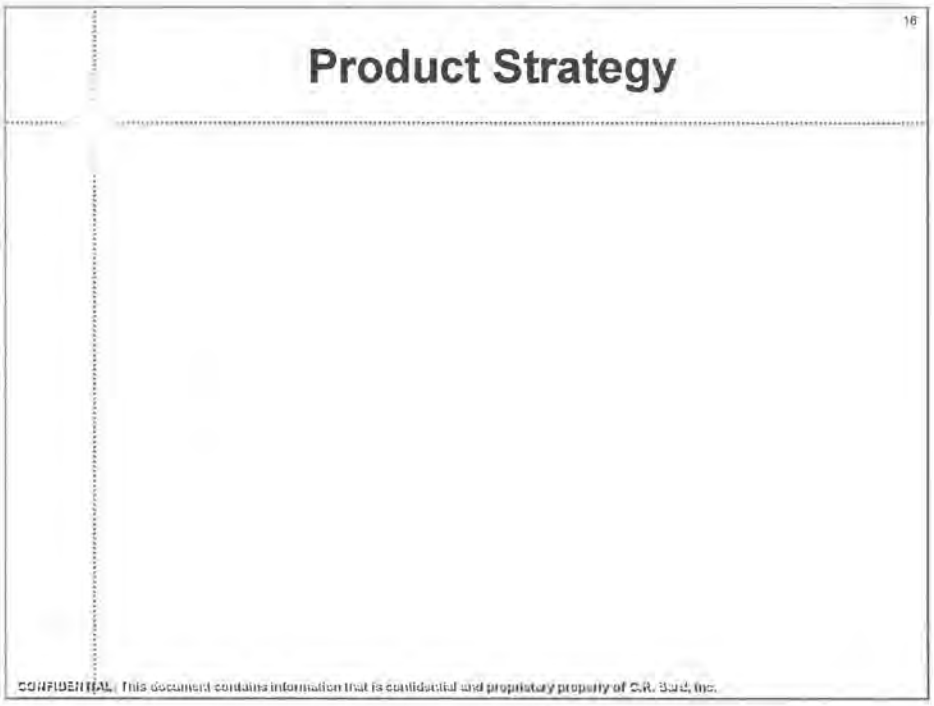
15

Is SNF Relevant?

- Cost Conscious Customers
  - VA Hospitals
  - Community Hospitals
  - Physician Owned Clinics
- Clinical Need
  - Certain types of patients
- With Everest BPV truly has Permanent and Optional Filters

SNF Revenue (MM)

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Product Strategy
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Product Strategy
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Filter Franchise Improvements
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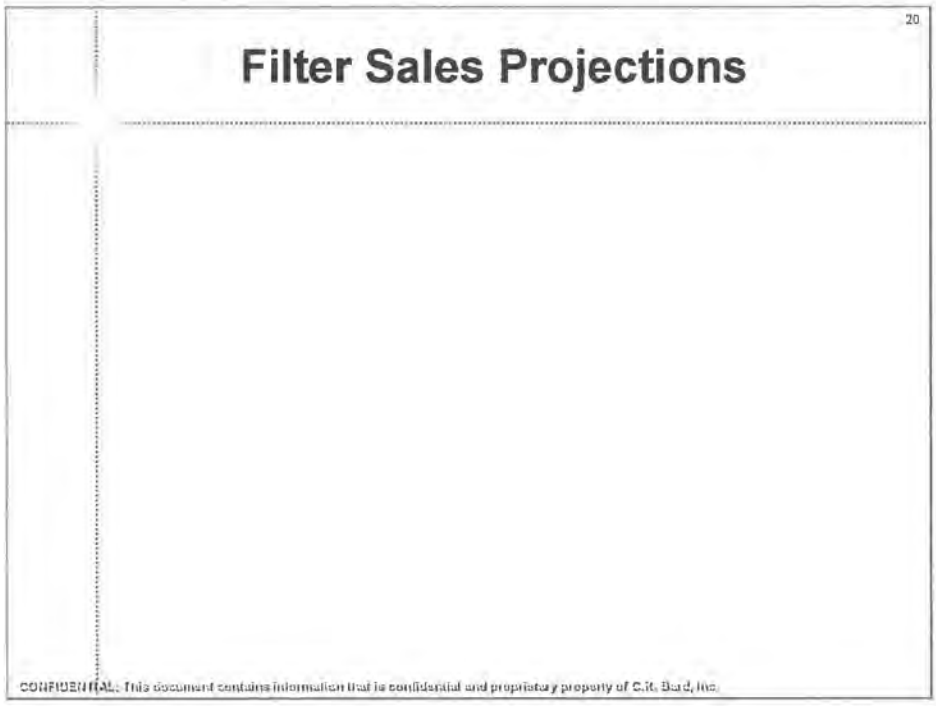
ASP Comparison

Optional	
G2	$1,270
OptEase	$1,278
Gunther-Tulip	$956
Celect	N/A
Non-weighted average	$1,183

Permanent	
TrapEase	$1,135
Bird's Nest	$1,071
VenaTech	$1,061
Greenfield	$940
Simon Nitinol	$902
Non-weighted average	$1,022


20
Filter Sales Projections
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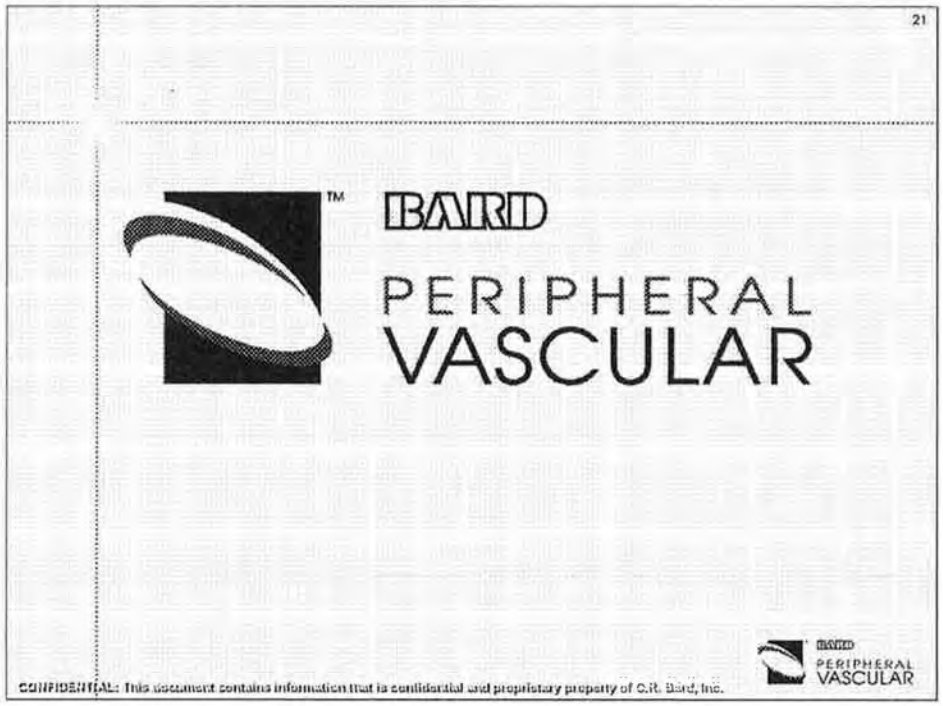
21
BARD
PERIPHERAL
VASCULAR
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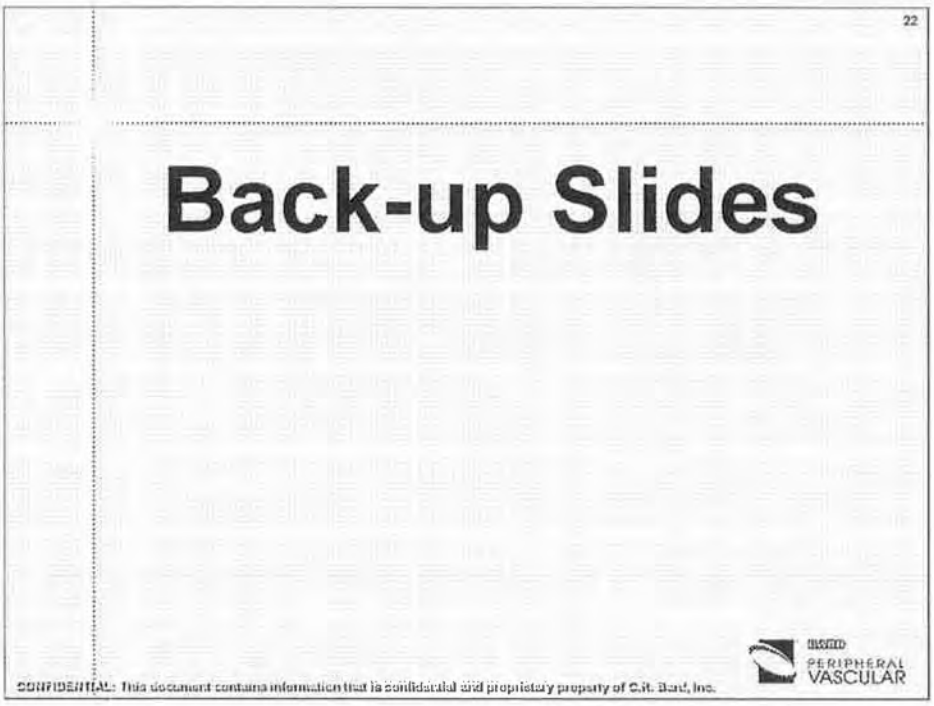
BARD
PERIPHERAL
VASCULAR


22
Back-up Slides
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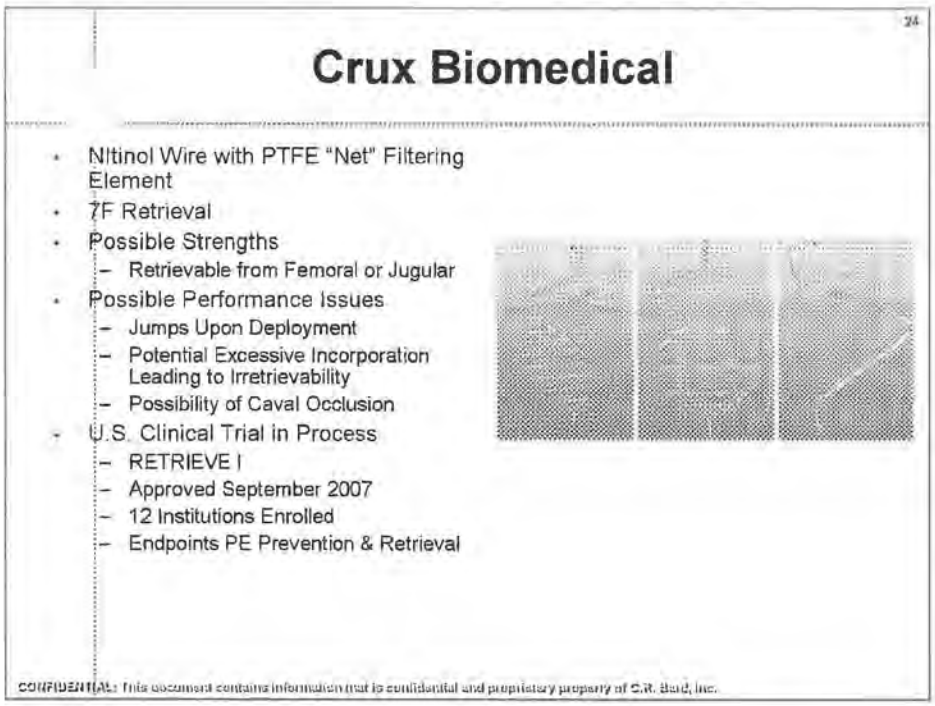
Snares

U.S. Standard Snare Market ($30M)

G2 EXPRESS®
VENA CAVA FILTER

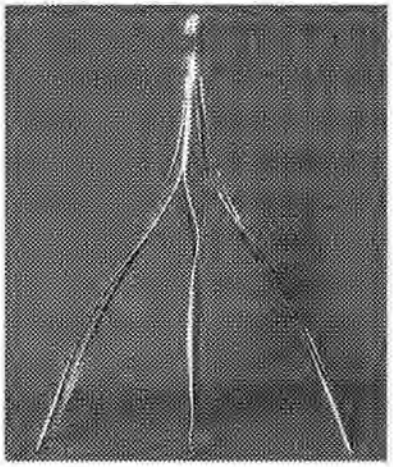


- Heard of downward jump
- Excessive incorporation issues
- Probably be occluder
- Trial is in progress in the US

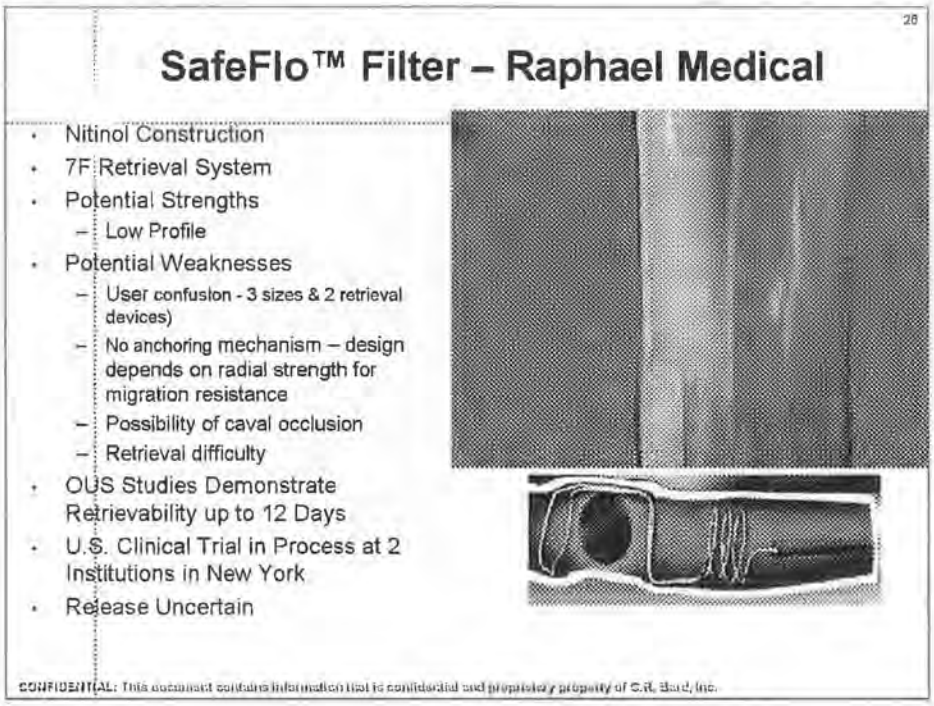
25

Option* LT (Rex Medical)

- Laser-Cut Nitinol Tube
- Single Level Conical Design
- Angiotech Signed Licensing Deal March 13
- Potential Strengths
  - 5F Profile
- Potential Weaknesses
  - Tilting an Issue
  - Possibility of Guidewire Entrapment
- Performance Similar to that of Gunther-Tulip
- 14 – 107 Day Retrievals OUS
- U.S. Clinical Trial in Process
  - Reports of Tilting
  - Retrieval Issues
  - Reports of 14 - 107 Day Indwell
  - Enrollment Complete Q2 2008
- U.S. Release Late 2008



- Something of a threat, low profile
- Gregg Pichler less than 50% success rate 3 weeks
- Made like TrapEase
- Tilting problem
- Venbrooks speaker
- US AIM/VEITH, 20 days mean, 6-175 days, paper at SIR
- Abbott, BSCI, Terumo
- Hooks twist, torquing cava



•3 sizes, wrong size chosen, downside of 3 different sized filters, too small embolus, too large perf,

•No fixation just radial force

•Flat filter with wires

•What is issue with flat filter element??? Occlusion.

•Eggbeater retrieval device… Raphael Medical characterize it like a eggbeater

•Heard FDA had issues with trial

List Prices

27

OptEase	$1,695 / $1,795
Celect	$1,395 / $1,300
G2	$1,395
SS Greenfield	$1,199
TrapEase	$1,195 / $1,295
Gunther-Tulip	$1,125
Vena Tech LP	$1,085
Ti Greenfield	$1,099
Bird's Nest	$1,049
Simon Nitinol	$1,035
Vena Tech	$895 / $995


28
EVEREST Commercialization
FDA concurrence Jan 15
Field communication
– IFU available 1/18
– Informational Webcast for Sales - Jan 21
Abstract presentation at SIR - Mar 15
EVEREST
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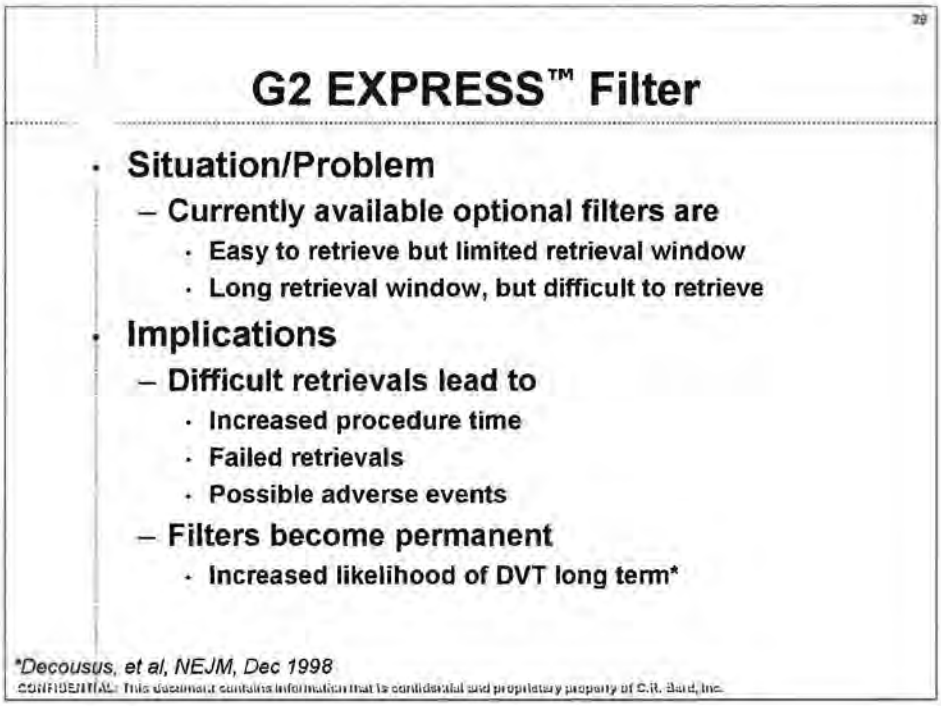
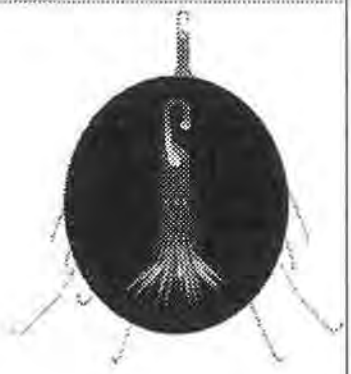


Speak to leveraging new indication to better meet customer needs

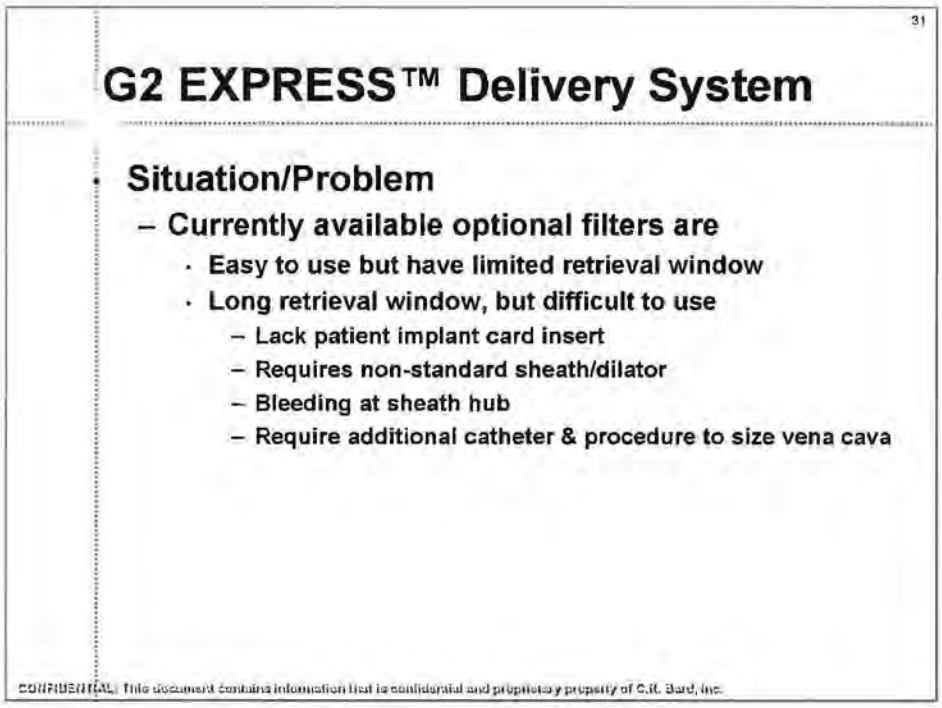
30

G2 EXPRESS™ Filter

- **Solution**
  - Add snare tip to the G2® Filter
- **Status/Action Plan**
  - DV & V Phase
  - Submit Special 510(K) - March
  - Introduce at SIR



G2 EXPRESS


31
G2 EXPRESS™ Delivery System
Situation/Problem
– Currently available optional filters are
· Easy to use but have limited retrieval window
· Long retrieval window, but difficult to use
– Lack patient implant card insert
– Requires non-standard sheath/dilator
– Bleeding at sheath hub
– Require additional catheter & procedure to size vena cava
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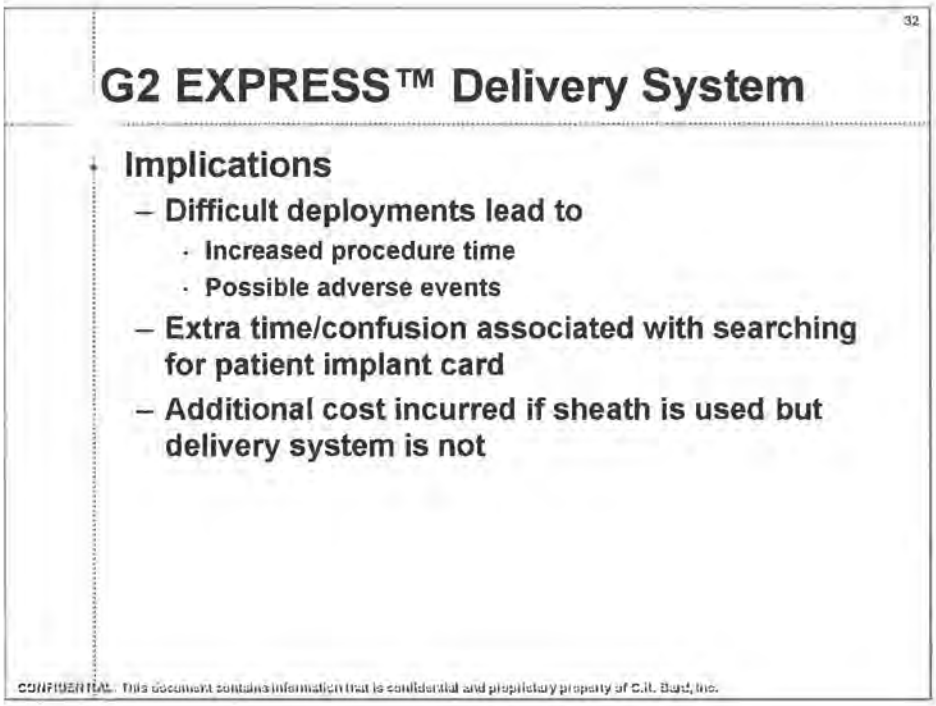
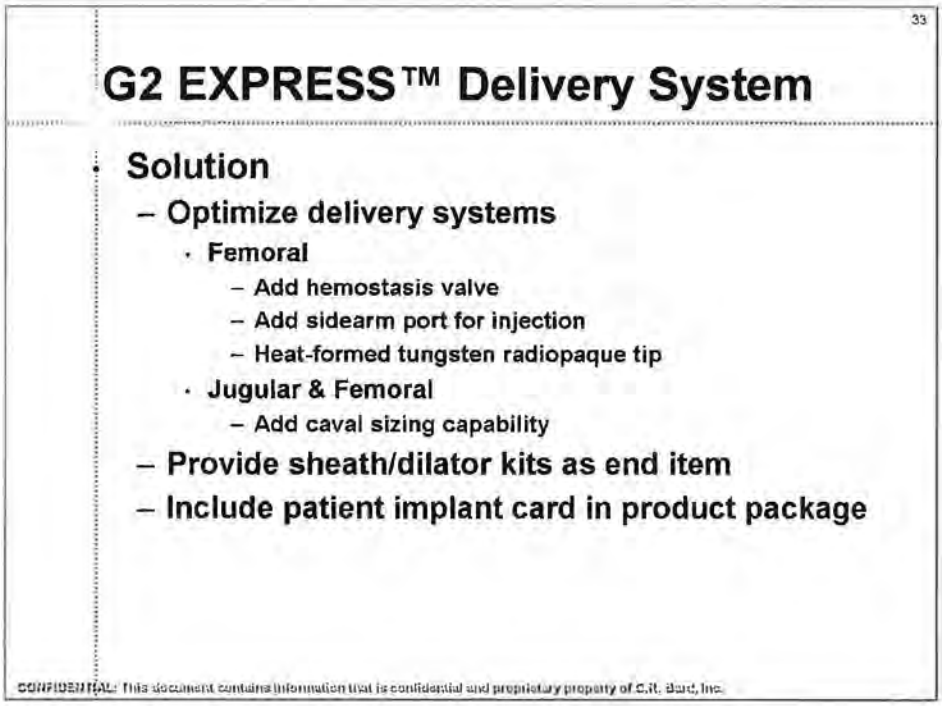


32

G2 EXPRESS™ Delivery System

- Implications
  - Difficult deployments lead to
    - Increased procedure time
    - Possible adverse events
  - Extra time/confusion associated with searching for patient implant card
  - Additional cost incurred if sheath is used but delivery system is not


33
G2 EXPRESS™ Delivery System
Solution
– Optimize delivery systems
· Femoral
– Add hemostasis valve
– Add sidearm port for injection
– Heat-formed tungsten radiopaque tip
· Jugular & Femoral
– Add caval sizing capability
– Provide sheath/dilator kits as end item
– Include patient implant card in product package
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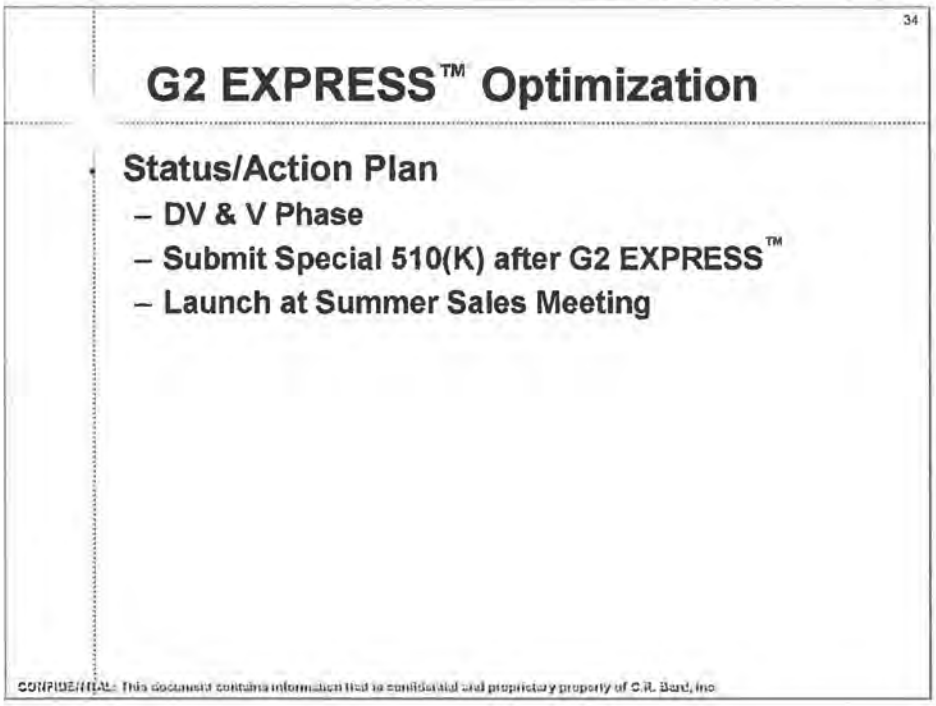
34
G2 EXPRESS™ Optimization
Status/Action Plan
– DV & V Phase
– Submit Special 510(K) after G2 EXPRESS™
– Launch at Summer Sales Meeting
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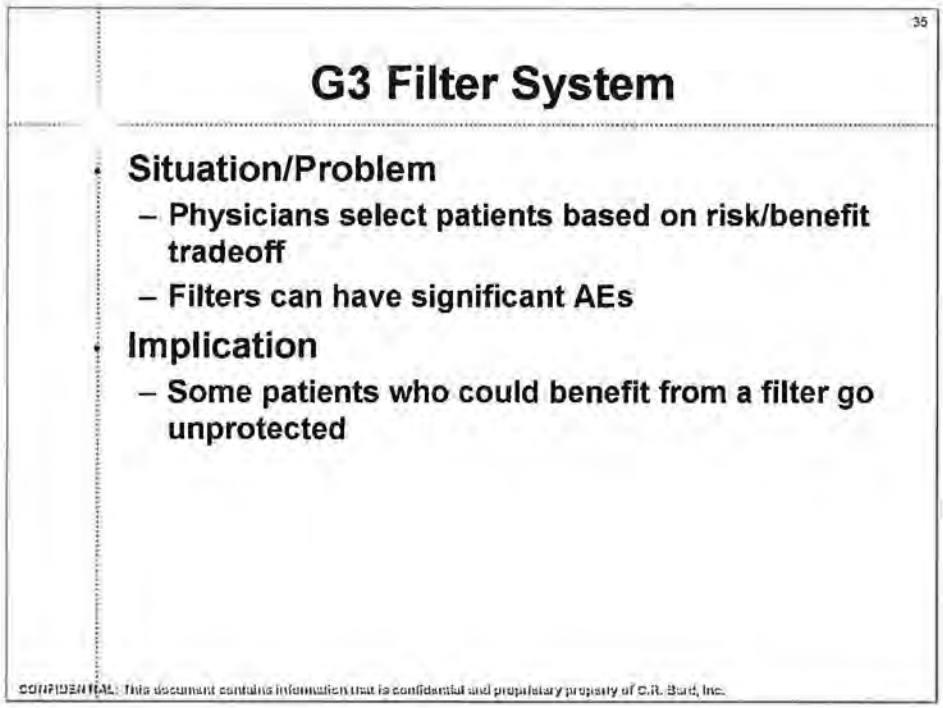
35
G3 Filter System
Situation/Problem
– Physicians select patients based on risk/benefit tradeoff
– Filters can have significant AEs
Implication
– Some patients who could benefit from a filter go unprotected
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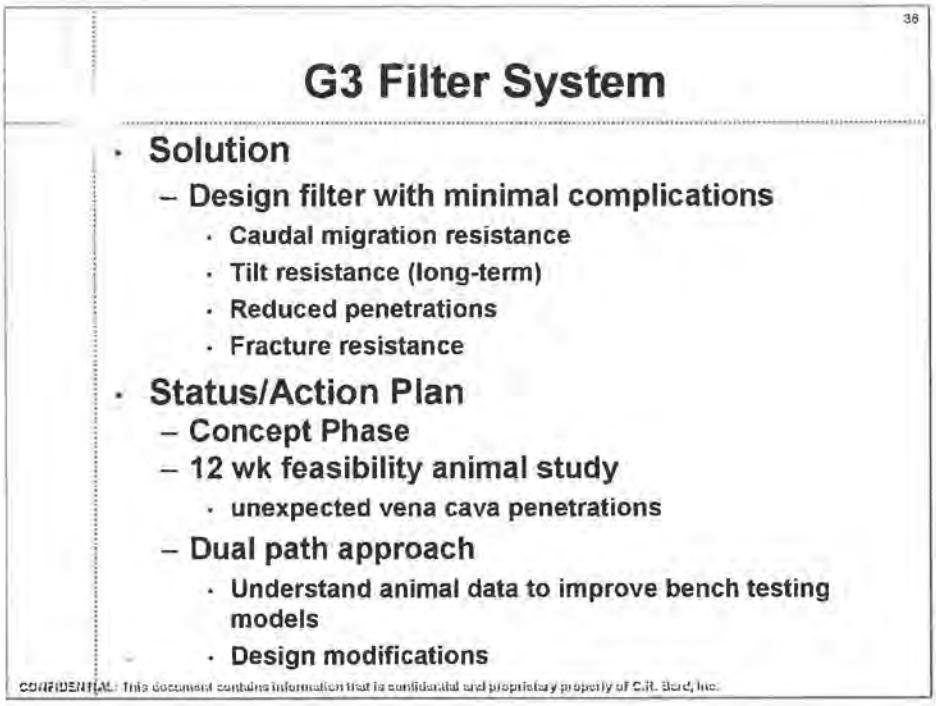
36
G3 Filter System
Solution
Design filter with minimal complications
Caudal migration resistance
Tilt resistance (long-term)
Reduced penetrations
Fracture resistance
Status/Action Plan
Concept Phase
12 wk feasibility animal study
unexpected vena cava penetrations
Dual path approach
Understand animal data to improve bench testing models
Design modifications
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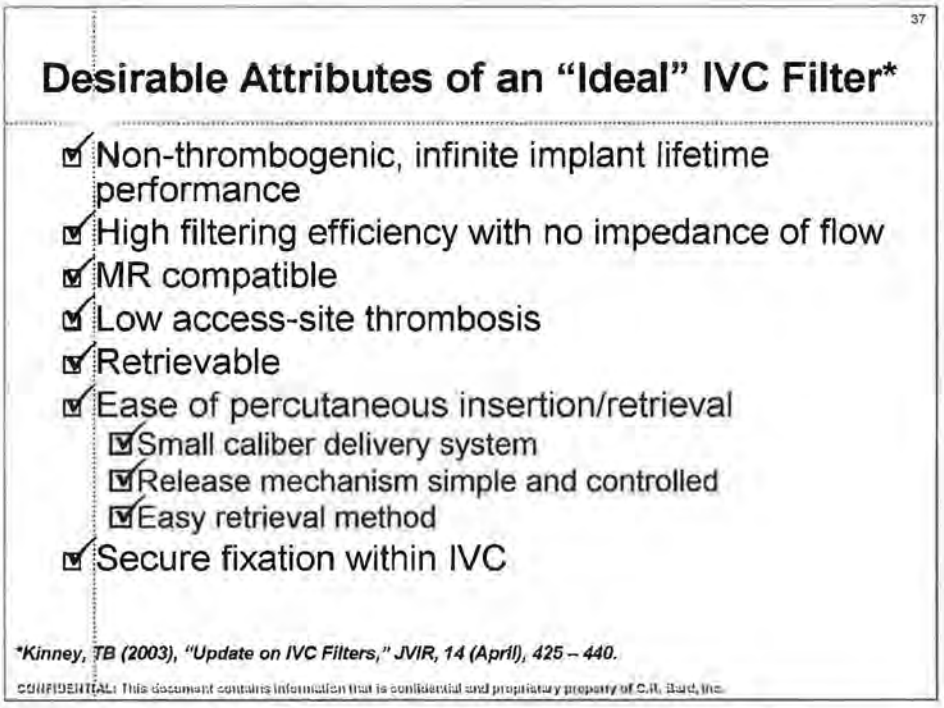
37
Desirable Attributes of an "Ideal" IVC Filter*
Non-thrombogenic, infinite implant lifetime performance
High filtering efficiency with no impedance of flow
MR compatible
Low access-site thrombosis
Retrievable
Ease of percutaneous insertion/retrieval
Small caliber delivery system
Release mechanism simple and controlled
Easy retrieval method
Secure fixation within IVC
*Kinney, TB (2003), "Update on IVC Filters," JVIR, 14 (April), 425 – 440.
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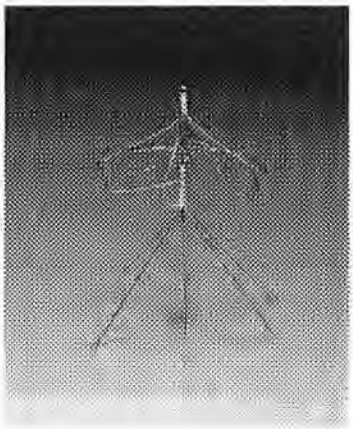
Filter NPD Update

Program Update	September Plan	March Plan
EVEREST	Q1/Q2 '08	Jan '08
G2 Express	Q2 '08	Q2 '08
G2 Express Filter	Q2 '08	4/15/08
G2EX Delivery System	Q2 '08	Q2 '08
G3 Filter	H1 2010	TBD

39

Simon Nitinol Filter



- First Nitinol Vascular Implant
- First Bi-Level Filter
- First Low-Profile 7F ID Delivery System
  - Indicated for R/L Femoral, Jugular, Subclavian and Antecubital Access
- Released in 1990 with Over 17 Years of Proven Efficacy
- Implanted in over 150,000 patients